wholesale acquisition cost for one of the injectible anti-emetic drugs specified in the proposed exception was reduced by the manufacturer by seventy-three percent. If the proposed exception were applied to this drug, the payment would provide a margin of over one hundred dollars for each dose administered and the outcome would be contrary to the stated intent of the proposal. The commenter believed that CMS could not have anticipated the perverse payment situation that would result under such an exception and recommended that CMS reconsider and withdraw the exception to the packaging rule for this class of drugs.

Response: We appreciate the commenters' support of our proposal to pay for the six 5HT3 products separately. We also recognize the concerns raised by a commenter informing us of the price reduction for one of the injectible products. However, we firmly believe that packaging some of the 5HT3 anti-emetic products and paying separately for others may negatively impact a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician. Therefore, we are finalizing our policy to pay separately for all six injectible and oral forms of anti-emetic products in CY 2005. We note that this policy only affects drugs of a particular class (in this case, 5HT3 anti-emetic products) that vary in their payment status (that is, packaged or paid separately), and our intent is not to generally standardize payment methodologies for separately payable drugs of the same class.

Comment: One commenter expressed operational concerns about billing for oral anti-emetics associated with chemotherapy. The commenter indicated that it will be extremely difficult to bill for these drugs when the same HCPCS codes are used for the drugs' use in nausea not associated with chemotherapy and requested that CMS consider establishing a separate HCPCS code or an edit that will only allow payment when a cancer diagnosis is on the claim.

Response: The following HCPCS codes are those hospitals use to report the six 5HT3 products irrespective of their use: J1260 (Injection, Dolasetron, Mesylate, 10 mg), Q0180 (Dolasetron Mesylate, 100 mg, oral), J1626 (Injection, Graniestron Hydrochloride, 100 mcg), Q0166 (Granisetron Hydrochloride, 1 mg, oral), J2405 (Injection, Ondansetron Hydrochloride, per 1 mg), and Q0179 (Ondansetron Hydrochloride 8 mg, oral). The policy discussed above applies only to the packaging status of these products, not to their coverage status. Hospitals should continue billing in accordance with existing coverage rules.

Comment: We received comments on the packaging status of several drugs, biologicals, and radiopharmaceutical agents where the commenters indicated that the items were incorrectly packaged and should be paid separately as sole source ''specified covered outpatient drugs.'' Specific items mentioned in the comments were HCPCS codes A9524, Q3010, J2790, and J7525. The commenters asserted that the median cost per day calculations for these products were based on inaccurate and incomplete hospital claims data because the hospitals were not likely to have been charging appropriately for the products or billing the correct number of units. One of the commenters also cited changes in HCPCS code descriptors and the lag time in hospitals updating their charge masters to reflect revised code descriptors as possible reasons for why the hospital claims data may be skewed and may not be reflective of hospitals' actual acquisition costs. Another commenter asserted that since many of these drugs were packaged in CY 2003, the claims data did not capture the drugs' actual costs. Commenters urged CMS to review only the ''correctly coded'' claims when determining median cost per day for these products, use external data to help determine appropriate payment rates, or pay for the drugs separately as sole source ''specified covered outpatient drugs'' since these items meet that definition. Another commenter requested that CMS retain the CY 2004 payments until there is enough data to accurately determine payment rates.

Response: We understand commenters' concerns about the median cost per day for these particular items. To determine which claims for drugs, biologicals and radiopharmaceuticals are ''correctly coded'' would require that we attempt to assess which claims indicate that the number of units billed were or were not clinically reasonable. Given variations among patients with respect to the appropriate doses, the variety of indications with different dosing regimens for some agents, our lack of information about how many doses were administered on a given day, the possibility of off-label uses, and our desire not to question the clinical judgment of the prescribing providers on these issues, we do not believe that an approach that attempts to identify and use only ''correctly coded'' claims is feasible. The hospital claims database is the best and most complete source of data we have for establishing median hospital costs for the services and items paid for under the OPPS.

In section III.B. of this final rule with comment period, we discuss comments concerning our methodology for units trimming. It is possible that some other approaches to units trimming could increase the derived cost per day for some drugs but could also result in decreases for some. For others, it could result in no difference for the drug in relation to the $50 threshold. As a test, we applied several different unit trim approaches to one of the codes for which we received comments and still did not achieve a median cost per day above $50. Nevertheless, we appreciate the thoughtful comments we have received on this topic and will consider the issue of units trimming in later development of our OPPS payment rates. For our final policy for CY 2005, however, we retain the methodology that we proposed. We will also encourage hospitals to carefully consider the descriptions of each HCPCS code when determining the number of units to bill for drugs, biologicals and radiopharmaceuticals. We will consider special efforts related to particular items. We would note, also, that the payment hospitals receive for a particular drug is based on the number of units billed. If a hospital underreports the number of units administered to a patient due to a misunderstanding about the definition of the code, the hospital will not receive the full amount to which it is entitled. Conversely, hospitals should not report more units than appropriate based on the coding description and the amount required to treat the patient.

3. Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs

Section 621(a)(1) of Pub. L. 108–173 amended section 1833(t) of the Act by adding a new subparagraph (14) that requires special classification of certain separately paid radiopharmaceutical agents and drugs or biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i), a ''specified covered outpatient drug'' is a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC exists and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not

included in the definition of ''specified covered outpatient drugs.'' These exceptions are:

• A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.

• A drug or biological for which a temporary HCPCS code has not been assigned.

• During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(i) of the Act, as added by section 621(a)(1) of Pub. L. 108–173, specifies payment limits for three categories of specified covered outpatient drugs in CY 2004. Section 1833(t)(14)(F) of the Act defines the three categories of specified covered outpatient drugs based on section 1861(t)(1) and sections 1927(k)(7)(A)(ii), (k)(7)(A)(iii), and (k)(7)(A)(iv) of the Act. The categories of drugs are ''sole source drugs,'' ''innovator multiple source drugs,'' and ''noninnovator multiple source drugs.'' The definitions of these specified categories for drugs, biologicals, and radiopharmaceutical agents under Pub. L. 108–173 were discussed in the January 6, 2004 OPPS interim final rule with comment period (69 FR 822), along with our use of the Medicaid average manufacturer price database to determine the appropriate classification of these products. Because of the many comments received on the January 6, 2004 interim final rule with comment period, the classification of many of the drugs, biologicals, and radiopharmaceuticals changed from that initially published. These changes were announced to the public on February 27, 2004, Transmittal 112, Change Request 3144. Additional classification changes were implemented in Transmittals 3154 and 3322.

We received 25 public comments associated with the January 6, 2004 interim final rule with comment period. These public comments are summarized under section V.B.4. of this preamble.

Section 1833(t)(14)(A) of the Act, as added by section 621(a)(1) of Pub. L. 108–173, also provides that payment for these specified covered outpatient drugs is to be based on its ''reference average wholesale price,'' that is, the AWP for the drug, biological, or radiopharmaceutical as determined under section 1842(o) of the Act as of May 1, 2003 (section 1833(t)(14)(G) of the Act). Section 621(a) of Pub. L. 108–173 also amended the Act by adding section 1833(t)(14)(A)(ii), which requires that:

• A sole source drug must, in CY 2005, be paid no less than 83 percent and no more than 95 percent of the reference AWP.

• An innovator multiple source drug must, in CY 2005, be paid no more than 68 percent of the reference AWP.

• A noninnovator multiple source drug must, in CY 2005, be paid no more than 46 percent of the reference AWP.

Section 1833(t)(14)(G) of the Act defines ''reference AWP'' as the AWP determined under section 1842(o) as of May 1, 2003. We interpreted this to mean the AWP set under the CMS single drug pricer (SDP) based on prices published in the Red Book on May 1, 2003.

For CY 2005, we proposed to determine the payment rates for specified covered outpatient drugs under the provisions of Pub. L. 108–173 by comparing the payment amount calculated under the median cost methodology as done for procedural APCs (described previously in the preamble) to the AWP percentages specified in section 1833(t)(14)(A)(ii) of the Act.

Specifically, for sole source drugs, biologicals, and radiopharmaceuticals, we compared the payments established under the median cost methodology to their reference AWP. We proposed to determine payment for sole source items as follows: If the payment falls below 83 percent of the reference AWP, we would increase the payment to 83 percent of the reference AWP. If the payment exceeds 95 percent of the reference AWP, we would reduce the payment to 95 percent of the reference AWP. If the payment is no lower than 83 percent and no higher than 95 percent of the reference AWP, we would make no change.

Comment: A few commenters strongly opposed the decrease in the payment floor for sole source specified covered outpatient drugs from 88 percent of AWP in CY 2004 to 83 percent of AWP in CY 2005. The commenters believed that the decrease was inappropriate and lacked sound policy justification. The commenters recommended that for CY 2005 the payment floor for sole source specified covered outpatient drugs be maintained at 88 percent of AWP. One commenter, however, was concerned about the proposed payment rate for HCPCS code J9395 (Injection, Fulvestrant, 25 mg), which is based on 83 percent of AWP instead of 85 percent of AWP that is the CY 2004 payment level. The commenter asserted that CMS's use of median cost data to establish appropriate payment rates for specified covered outpatient drugs is faulty for this drug because of concerns about the accuracy of the hospital median cost data. The commenter also indicated that several payment changes affecting this drug were likely to have created a significant degree of confusion among hospitals that may have negatively skewed hospital median cost data and led CMS to correlate the data to an AWP-based payment percentage that is too low. Another commenter urged CMS to create an exceptions process that would provide for appropriate adjustments within the MMA-specified payment corridor upon submission of data documenting potential access problems or a payment rate significantly lower than the acquisition cost of the drug. The commenter indicated that creating such an approach would help to minimize disruption to patient access to drugs in the hospital outpatient setting. To the contrary, several commenters were pleased with the payment rates for certain products at 83 percent of their AWPs.

Response: Section 621(a) of Pub. L. 108–173 is very specific in requiring that a sole source drug must be paid no less than 83 percent and no more than 95 percent of the reference AWP in CY 2005. We used the 83 percent of AWP as the payment floor to set payment rates for sole source drugs, unless payments based on median costs were higher, as we lack any data to determine what would be the appropriate payment level between 83 percent and 95 percent of AWP for all sole source drugs. We set up a payment floor to avoid paying for these drugs at different arbitrarily determined payment levels. We note that if data show that the payment rate for a drug falls between the 83 percent floor and 95 percent ceiling, the drug is paid at the payment rate.

We have responded to comments about the relative hospital data from our claims above and in other sections of this preamble. While we certainly share the desire to provide beneficiaries with access to the drugs that are reasonable and necessary for the treatment of their conditions, we do not agree with the comments that we should pay above the 83 percent floor established by the MMA for sole source drugs if the median hospital cost falls below this floor. We believe the intent of the law is to use hospital cost data as the best available information in setting the payment rates for most items paid for under the OPPS. In the case of sole source specified covered outpatient drugs, the MMA provides for a floor of 83 percent of the reference AWP for those items for which the payment based on relative hospital costs would fall below 83 percent of the AWP and a ceiling of 95 percent of the reference AWP for items where the relative

hospital costs from our claims data exceed that amount. We are not convinced that the 83 percent AWP floor is a barrier to appropriate treatment.

Comment: One commenter, the manufacturer of AGGRASTAT®, requested that CMS convert the current temporary outpatient HCPCS code C9109 (Injection, Tirofiban HCl, 6.25 mg) to a permanent national HCPCS code with a base dose of 5 mg and continue to maintain the permanent national HCPCS code J3245 (Injection, Tirofiban HCl, 12.5 mg). The commenter asserted that HCPCS codes with units of 5 mg and 12.5 mg would properly reflect the actual doses of AGGRASTAT® that currently exist in the market.

Response: For 2005, the National HCPCS Panel decided to delete HCPCS codes C9109 and J3245 and create a new HCPCS code J3246 (Injection, Tirofiban HCl, 0.25 mg). We hope that the creation of this new HCPCS code will ameliorate the commenter's concerns about appropriate coding for this product.

Comment: We received a number of comments on the packaging status of HCPCS codes J7505 (Muromonab-CD3, parenteral, 5 mg) and J9266 (Pegaspargase, single dose vial). The commenters stated that these two products were incorrectly packaged because the data used to determine packaging status were flawed and requested that both products be paid separately as sole source drugs at a rate between 83 percent and 95 percent of their AWPs.

Response: There were several drugs and biologicals that we proposed to package in the proposed rule, including the two products mentioned in the comments. However, when we recalculated their median costs per day using all of the hospital claims from CY 2003 used for this final rule with comment period, we determined that their median costs per day were greater than $50. Therefore, for CY 2005, we will pay for these drugs and biologicals separately. Items that meet the definition of ''specified covered outpatient drugs'' (SCOD) will be paid according to the payment methodologies established in the MMA, and payment for items that do not meet the definition will be based on their median unit cost. Table 25 lists the drugs and biologicals that were proposed as packaged drugs and biologicals but will be paid separately in CY 2005. The table also indicates the methodology that will be used to determine their APC payment rates in CY 2005.

Table 25. - Drugs and Biologicals with Packaging above $50 Threshold (Proposed as packaged items but will be paid separately in CY 2005)

HCPCS	Description	CY 2005 Payment Methodology
J0743	INJ, CILASTATIN SODIUM; IMIPENEM, PER 250 MG	Median based
J0900	INJ, TESTOSTERONE ENANTHATE AND ESTRADIOL VALERATE, UP TO 1 CC	Median based
J1455	INJ, FOSCARNET SODIUM, PER 1000 MG	Median based
J2760	INJ, PHENTOLAMINE MESYLATE, UP TO 5 MG	Median based
J1325	INJ, EPOPROSTENOL, 0.5 MG	SCOD
J7505	MUROMONAB-CD3, PARENTERAL, 5 MG	SCOD
J9050	CARMUSTINE, 100 MG	SCOD
J9165	DIETHYLSTILBESTROL DIPHOSPHATE, 250 MG	SCOD
J9266	PEGASPARGASE, PER SINGLE DOSE VIAL	SCOD

Comment: One commenter was concerned about the proposed payment rates for HCPCS codes A9502 (Supply of radiopharmaceutical diagnostic imaging agent, technetium Tc 99m tetrofosmin, per unit dose) and Q3005 (Supply of radiopharmaceutical diagnostic imaging agent, technetium Tc-99m mertiatide, per mci). The commenter indicated that payment corrections made for these two products in the February 27, 2004 CMS Transmittal 113 resulted in significant payment reductions. The commenter was concerned that significant payment fluctuations and reductions were counter-productive to the provision of quality care and will negatively impact the operational viability of nuclear medicine departments. Therefore, the commenter urged CMS to reconsider their proposed payments for these two products.

Response: We understand the commenter's concern about the impact of fluctuations in payment rates for HCPCS codes A9502 and Q3005. However, we note that the payment rates that were listed in the January 6, 2004 interim final rule with comment period for these products were calculated using incorrect reference AWPs as indicated in the February 27, 2004 CMS Transmittal 113. Therefore, we made corrections to the AWPs for these products and recalculated their payment rates according to the payment methodology required by the MMA for sole source ''specified covered outpatient drugs''.

Comment: One commenter requested that CMS support a decision by the HCPCS Alpha-Numeric Editorial Panel to issue separate permanent and universal drug codes for echocardiography contrast agents for which applications have been submitted. Specifically, the commenter recommended that CMS support the application submitted for the creation of a J-code for Definity, which is currently being reported as HCPCS code C9112 (Injection, perflutren lipid microsphere, per 2 ml vial).

Response: Decisions regarding the creation of permanent HCPCS codes are coordinated by the National HCPCS Panel. Comments related to the HCPCS code creation process and decisions made by the National HCPCS Panel are

outside the scope of this rule; therefore, we will not respond to this comment. We note that until a J-code is established for this product, hospitals can continue to bill for this product using the HCPCS code C9112.

Comment: Several commenters expressed concern about the proposed payment for intravenous immune globulin. They were concerned that CMS calculated the reference AWP for this code using AWPs for one or more products that were no longer commercially available. For example, Carimune and Panglobulin were removed from the market and replaced with Carimune NF and Panglobulin NF, respectively. The commenters requested that CMS review the current pricing data on the brand products that are currently in the market place and recalculate payment for IVIG as a sole source specified covered outpatient drug. Another commenter was concerned about the proposed payment rate for HCPCS code J7198 (Anti-inhibitor, per IU). The commenter indicated CMS calculated the reference AWP for this code using an AWP for a product called Autoplex that was discontinued from the market in May 2004 and recommended that CMS calculate payment for this HCPCS code using cost data associated with the product Feiba VH that currently exists in the market.

Response: We agree with the comments and accordingly recalculated the base AWP for HCPCS code J1563 (Immune globulin, intravenous, 1 g) excluding AWPs for the two discontinued products, Panglobulin and Carimune. Similarly, we excluded the AWP for the discontinued product, Autoplex, when redetermining the base AWP for HCPCS code J7198 (Anti-inhibitor, per IU). We then recalculated their payment rates as sole source ''specified covered outpatient drugs.'' We note that these changes resulted in an increase in the base AWPs for both products.

Comment: One commenter, the maker of the product billed under HCPCS code C9201 (Dermagraft, 37.5 cm2), requested that CMS set its CY 2005 payment rate under the OPPS identical to the payment rate in the physician office setting. The commenter anticipated a payment rate of $574.41 (third quarter ASP plus 6 percent) when it is used in the physician office setting during CY 2005; however, the proposed payment rate as a sole source drug under the OPPS was $529.54. The commenter indicated that Dermagraft's cost to all customers is identical regardless of the site of service and establishing a payment rate under the OPPS below the cost of the product to hospitals would hinder their access to medical technologies for which they will not recover their costs. Additionally, we received comments from an association representing a group of specialty hospitals and a professional association expressing concern about the proposed payment level for HCPCS code J3395 (Injection, verteporfin, 15 mg). The commenters indicated that the payment rate for this product is significantly less than the acquisition cost for outpatient facilities and requested that CMS pay for it at a rate that covers the cost of acquiring the drug. The commenter also stated that accurate pricing information for the drug should be available when CMS receives final data from the manufacturer on October 31, 2004 and that the final OPPS payment rate should be reflective of the pricing data.

Response: The products described by HCPCS codes C9201 and J3395 meet the definition of sole source ''specified covered outpatient drugs.'' The MMA specifies the methodology that determines payment for this group of drugs under the OPPS where, for CY 2005, sole source drugs must be paid between 83 percent and 95 percent of their reference AWP. Since payments for these two products based on the median cost methodology were less than 83 percent of their AWPs, their CY 2005 payment levels were established at 83 percent of their AWP. In these cases, we believe the statute specifically addresses the payment methodology for these drugs.

Comment: A few commenters were concerned about the proposed payment rates for some separately payable drugs and biologicals that did not fall under the category of ''specified covered outpatient drugs.'' These products would be either paid as pass-through items or their payment rates were based on median cost data; however, the commenters requested that the products be paid as sole source ''specified covered outpatient drugs.'' One of the commenters requested that external data be used to correct the payment rate for their product. Several rationales were cited for this request to change the payment methodology, such as the use of inaccurate and incomplete hospital claims data to determine payment rates that are lower than actual hospital acquisition costs and eliminating payment differentials between drugs of the same class.

Response: We believe that the MMA defines the items that are to be considered ''specified covered outpatient drugs'' for payment purposes under the OPPS, and these drugs do not meet the definition. We also recognize that classifying these products as sole source ''specified covered outpatient drugs'' would increase their payments; however, we are not convinced that the payment rates for these products calculated under current methodologies are insufficient.

In developing our August 16, 2004 proposed rule, there was one sole source item, Co 57 cobaltous chloride (HCPCS code C9013), for which we could not find a reference AWP amount. However, we had CY 2003 claims data for HCPCS code C9013, and therefore, we proposed to derive its payment rate using its median cost per unit. We requested comments on our proposed methodology for determining the payment rate for HCPCS code C9013. We received a few comments in response to our proposal.

Comment: The manufacturer of the product billed under HCPCS code C9013 (Supply of Co 57 cobaltous chloride, radiopharmaceutical diagnostic imaging agent), Rubatrope, along with other commenters, indicated that Rubatrope is an FDA-approved radiopharmaceutical and a sole source drug that meets the definition of a ''specified covered outpatient drug;'' therefore, it should be paid between 83 percent and 95 percent of AWP. The manufacturer of Rubatrope indicated that it had experienced problems with the production of this product in the past 2 years and thus production was discontinued. However, the product will be commercially available from November 2004. The commenter also indicated that it would send CMS an AWP for this product once it becomes available. Therefore, for CY 2005, the commenters strongly urged CMS to establish payment for C9013 as a sole source drug at 83 percent of AWP.

Response: We understand the commenters' concern about the payment rate for this product and note that HCPCS code C9013 was considered a sole source ''specified covered outpatient drug'' in the proposed rule. However, as we were not able to determine a reference AWP for this product, we based its proposed payment rate on its median cost from the claims data. At the time of the publication of this final rule, we were still unable to find an AWP for this product, and thus, in the absence of an AWP for this product, as proposed we will use the product's median cost to base its CY 2005 payment rate. However, if we determine an AWP for HCPCS code C9013, we will issue a change to its payment accordingly in a quarterly update of the OPPS.

We note that there are three radiopharmaceutical products for which

we proposed a different payment policy in CY 2005. These products are represented by HCPCS codes A9526 (Ammonia N–13, per dose), C1775 (FDG, per dose (4–40 mCi/ml), and Q3000 (Rubidium–Rb–82). Radiopharmaceuticals are classified as a ''specified covered outpatient drug'' according to section 1833(t)(14)(B)(i)(I) of the Act and their payment is dependent on their classification as a single source, innovator multiple source, or noninnovator multiple source product as defined by sections 1927 (k)(7)(A)(iv), (ii), and (iii) of the Act. Upon further analysis of these items, we determined that these three products do not meet the statutory definition of a sole source item or a multiple source item. Pub. L. 108–173 requires us to pay for ''specified covered outpatient drugs'' using specific payment methodologies based on their classification and does not address how payment should be made for items that do not meet the definition of a sole source or multiple source item. Therefore, in the August 16, 2004 proposed rule, we proposed to set the CY 2005 payment rates for these three products based on median costs derived from CY 2003 hospital outpatient claims data, which would reflect hospital costs associated with these products. With regard to HCPCS code A9526, we have no hospital outpatient cost data for this HCPCS code. We received correspondence from an outside source stating that Rubidium–Rb–82 (HCPCS code Q3000) is an alternative product used for procedures for which Ammonia N–13 is also used and these two products are similar in cost. Therefore, we proposed to establish a payment rate for Ammonia N–13 that is equivalent to the payment rate for Rubdium Rb–82.

We listed the proposed CY 2005 payment rates for these three items in Table 25 of the proposed rule (69 FR 50507), requested comments on the proposed payment rates and invited commenters to submit external data if they believe the proposed CY 2005 payment rates for these items do not adequately represent actual hospital costs.

We received many public comments on the proposed payment rates for the three items.

Comment: Many commenters were concerned about the proposed reduction in the payment rate for FDG in CY 2005. They stated that FDG meets the definition of ''specified covered outpatient drugs,'' and the MMA requires that ''specified covered outpatient drugs'' be classified as sole source drugs, innovator multiple source drugs, or noninnovator multiple source drugs, and be reimbursed according to a percentage of the reference AWP during CY 2005. Several commenters understood the difficulty CMS had in classifying FDG into one of the three categories of ''specified covered outpatient drugs.'' However, one of the commenters was concerned that CMS abandoned the methodology prescribed by the MMA and created another payment category for ''specified covered outpatient drugs,'' which the commenter believed is outside the scope of the MMA.

A commenter suggested that CMS assign FDG to the category that most closely reflects the underlying regulatory and economic environment for the production of FDG, which is the innovator multiple source drug category. The commenter explained that the production and sale of FDG is unusual in that the FDA does not yet require an approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). The commenter also stated that the FDA is currently drafting special criteria to govern NDAs and ANDAs for the production and marketing of FDG, and eventually, manufacturers will be required to submit either an NDA or ANDA in order to sell FDG. Right now, there are no approved ANDAs or ''generics'' for FDG, and none of the FDA approved products is therapeutically equivalent. The commenter indicated that FDG is sold commercially by at least three manufacturers and is produced by numerous hospitals and academic medical centers for their own use, thus making it a multiple source drug. However, until the FDA finalizes its requirements for NDAs and ANDAs for FDG and all manufacturers have an opportunity to comply with those regulations, all FDG marketed in the United States should be considered a ''brand'' version. Although the different FDG products distributed are not rated as equivalent by the FDA, FDG was originally marketed under an NDA, and currently there are multiple distributors. Thus, although FDG does not meet all aspects of the multiple source innovator drug definition, given the inaccuracies of the hospital outpatient claims data, this commenter, along with several others, recommended that FDG be paid under the MMA at 68 percent of its AWP. Alternatively, some commenters requested that CMS keep the CY 2005 payment for FDG at its CY 2004 level until the completion of the GAO hospital acquisition cost survey, which will allow for a more reliable basis for setting payment based on average acquisition cost. One commenter stated that CMS should use external data submitted by hospitals to determine the true costs of this product. External data from a survey of 2002 nuclear medicine costs reported by hospitals were submitted, and the results indicated that median cost to hospitals for one dose of FDG is $425. Another commenter stated that their current cost for administering one dose of FDG to patients receiving PET scans is $450 and that CMS should research real market costs for this product before reducing payment by $126 from the current CY 2004 payment rate

The commenters all agreed that CMS should not use CY 2003 hospital claims data to calculate payment for FDG in CY 2005 because the reported data fails to accurately capture the actual acquisition cost to hospitals along with all the reasonable costs needed to safely prepare, store, administer, and dispose of the product. Commenters indicated that the HCPCS code descriptor for C1775 is written in a way that requires hospitals to use the same code to report FDG with a concentration of 4mci/ml as they use to report FDG with a concentration of 40 mci/ml, thus making the claims data unreliable, and also, hospitals did not have clear billing and charging guidance. Thus, the commenters claimed that the FDG data from CY 2003 are a flawed basis upon which to make a payment determination and would significantly underpay hospitals. Commenters noted that a reduction in payment for FDG to the proposed payment rate would limit utilization and access to FDG PET because of the financial losses the providers will suffer.

Response: We appreciate these thoughtful comments on our proposed payment rate for FDG. Based on the unique regulatory processes that affect the manufacturing and marketing of FDG, we believe that it is reasonable for us to classify FDG as an innovator multiple source drug. Therefore, we will not reinstate the HCPCS code C9408 (FDG, brand, per dose), which we inadvertently deleted as stated in the October 2004 Update of the OPPS (CMS Transmittal 290). In CY 2005, hospitals should use C1775 to bill for all FDG products.

With respect to calculating payment for FDG in CY 2005, the MMA requires that an innovator multiple source drug must be paid no more than 68 percent of the reference AWP. The MMA sets forth a payment ceiling for the brand innovator multiple source drugs, but does not provide a payment floor for them. We believe that the intent of the statute is to use available hospital

claims to set payment rates for most items paid under OPPS; therefore, we apply the ceiling only when the payment for an item based on the median hospital cost for the drug exceeds the ceiling. As we described in section V.A.3.a. of this final rule with comment period, for innovator multiple source drugs, we set the payment rate at the lower of the payment rate calculated under the standard median cost methodology or 68 percent of the AWP. We have applied this methodology to all of the other innovator multiple source drugs; therefore, we do not believe that it would be appropriate for us to exempt FDG from this methodology and pay for it at 68 percent of AWP, the ceiling for innovator products. We believe that basing payment for this item on relative hospital costs, with the application as appropriate of the previously mentioned ceiling, not only meets the intent but also the requirements of the MMA. The payment rate for C1775 in CY 2005 will be $221.11.

Comment: The manufacturer of CardioGen–82, also known as Rubidium Rb–82, along with other commenters asserted that this product does meet the classification of a sole source drug as defined by the MMA. The commenters indicated that FDA approval for this product was received under an NDA, and there is currently only one manufacturer of the Cardiogen–82 generators used to produce Rubidium Rb–82. Also, there is no FDA-approved generic product for Rubidium Rb–82. One of the commenters indicated that a survey was conducted to obtain data on actual hospital costs for Rubidium Rb–82, which showed that the median per dose cost to hospitals was $244.73. Thus, the commenter believed that CMS hospital cost data were flawed and do not represent true hospital costs; therefore, the hospital claims cost data should not be used to set the payment rate for Rubidium Rb–82 in CY 2005. Other commenters indicated that median cost data used by CMS to calculate the payment rate for Rubidium Rb–82 underreport the actual and reasonable hospital costs needed to safely prepare, store, administer, and dispose of the product. The commenters urged CMS to recognize HCPCS code Q3000 (Supply of radiopharmaceutical diagnostic imaging agent, Rubidium Rb–82, per dose) as a sole source drug and set its payment at 83 percent of its AWP, or at minimum, retain the CY 2004 payment rate.

Response: We appreciate these comments. Based on further evaluation of the appropriate classification for this product, we agree with the commenters that Rubidium Rb–82 should be classified as a sole source product. Therefore, payment for Q3000 will be made at 83 percent of AWP as its payment based on the median cost methodology is less than 83 percent of AWP. The payment rate for Rubidium Rb–82 in CY 2005 will be $153.39 per dose.

Comment: Numerous commenters were concerned about the proposed payment rate for HCPCS code A9526 (Ammonia N–13, per dose). Some of the commenters stated that CMS proposed to treat HCPCS codes Q3000 (Rubidium Rb–82, per dose) and A9526 under a ''presumptive functional equivalence'' in setting the same payment rate for these products when they are not functionally equivalent. It was also stated that Rubidium Rb–82 and Ammonia N–13 are used for similar procedures, but they have different costs, clinical composition, and utilization patterns. Another commenter indicated that Rubidium Rb–82 significantly differs from the other PET radiopharmaceuticals as it is produced by a radionuclide generator system, compared to FDG and Ammonia N–13 that are made in cyclotrons. A commenter also stated that Ammonia N–13 has no commercial vendors; whereas, Rubidium Rb–82 is produced and distributed by one commercial vendor. Some commenters suggested that CMS pay for A9526 separately, similar to other ''specified covered outpatient drugs.'' On the other hand, other commenters recommended that, in the absence of reliable cost data or a published AWP, CMS should use the cost of FDG as a proxy for the cost of Ammonia N–13, since these products have equivalent production costs.

Response: We recognize the concerns raised by commenters about our proposal to pay for Ammonia N–13 at the same payment rate as Rubidium Rb–82. We acknowledge that Ammonia N–13 meets the definition of ''specified covered outpatient drugs;'' however, we have not been able to determine an AWP for this product. Thus, we cannot set a payment rate for this product based on a percentage of its AWP. While some of the commenters recommended that we set the payment rate for Ammonia N–13 at the same level as that for FDG, we are aware this would give rise to the same concerns raised by commenters regarding payment for Ammonia N–13 and Rubidium Rb–82. Therefore, we are not adopting our proposed payment policy for Ammonia N–13. Based on the complete CY 2003 hospital claims data that were used for this final rule with comment period, we were able to identify claims submitted for Ammonia N–13; therefore, for CY 2005, we will use median cost derived from the claims data to set the payment for this product. The CY 2005 payment rate for A9526 will be $109.86 per dose.

Comment: A number of commenters, including several cancer research centers and trade associations representing the radionuclide and radiopharmaceutical industry, biomedical science, and the biotechnology industry, as well as the manufacturers of Bexxar (billed using HCPCS codes C1080, C1081, and G3001) and Zevalin (billed using HCPCS codes C1082 and C1083), expressed concern that 83 percent of AWP is insufficient to reimburse hospitals for the cost of acquiring Zevalin and Bexxar. Several commenters, including the manufacturer of Zevalin, were concerned that the proposed payment rates for Zevalin are inadequate to facilitate patient access to this critical therapy. One commenter stated that, because Zevalin is a radioimmunotherapy, its purchase and use are subject to state regulatory safeguards that limit its availability in the oncology practices; therefore, its access in the hospital outpatient setting is crucial. The commenter urged CMS to maintain the 2004 payment rates for Zevalin, which are at 88 percent of AWP, into CY 2005, and indicated that this stability would make treatment with Zevalin more economically feasible for hospitals.

One commenter, the manufacturer of Bexxar, expressed concern about what they identified as several ''inequities'' in the coding and proposed payments for Bexxar and Zevalin. Specifically, the commenter pointed out that the payment proposed for Bexxar in CY 2005 is more than $1500 less than the payment proposed for Zevalin. This commenter further recommended that payment for Bexxar be set at its wholesale acquisition cost, which is $19,500, or 95 percent of the RAWP, which would be $22,230. Several commenters indicated that CMS has the option to exceed the floor of 83 percent of AWP established under the MMA for sole source specified covered outpatient drugs, which would enable CMS to set a rate for Bexxar and Zevalin commensurate with their cost.

Two commenters recommended that CMS consider external data where available to supplement its payment determinations for Bexxar and Zevalin.

Response: We share the commenters' concerns that Medicare payment rates not be a barrier to beneficiary access to radioimmunotherapy for the treatment of non-Hodgkins lymphoma. However, we do not agree with the comments that we should set the OPPS payment rates

for Zevalin and Bexxar based on their CY 2004 payment levels, on external data, on their WAC, or on any payment amount other than that which is consistent the designation of radiopharmaceuticals in the MMA as specified covered outpatient drugs.

Zevalin and Bexxar are radiopharmaceuticals, and the MMA includes them as ''specified covered outpatient drugs'' for the OPPS payment purposes. Each meets the definition of a sole source drug. We believe the intent of the law is that we set payment rates for most items paid for under the OPPS using hospital cost data from the best and most recent information available, unless the statute directs otherwise, as in the case of drugs with pass-through status or new drugs without HCPCS codes. The MMA provides a floor of 83 percent of the reference AWP in CY 2005 for sole source specified covered outpatient drugs for which payment based on relative hospital costs would be less. Similarly, the MMA provides a cap of 95 percent of the reference AWP in CY 2005 for sole source specified covered outpatient drugs for which payment based on relative hospital costs would be higher. The statute provides a payment floor and ceiling for sole source ''specified covered outpatient drugs,'' at no lower than 83 percent of AWP or higher than 95 percent of AWP; the statute does not require a payment at some intermediate level that falls between 83 percent and 95 percent of AWP.

Payment for Zevalin based on relative hospital costs drawn from CY 2003 claims data would fall below 83 percent of the reference AWP. As we did in the case of other sole source drugs for which payment based on hospital claims would be lower than 83 percent of AWP, we proposed to set payment for Zevalin at 83 percent of the reference AWP. We also proposed to set payment for Bexxar in CY 2005 as a sole source radiopharmaceutical at 83 percent of AWP because, like Zevalin, it is a radiopharmaceutical and, therefore, a sole source specified covered outpatient drug under the MMA. We discuss in section V.G. of this final rule with comment period that we are making final our proposal to treat radiopharmaceuticals the same as we treat drugs and biologicals for purposes of ratesetting, with two exceptions: We will set payment for new radiopharmaceuticals for which we have no claims data, and for new radiopharmaceuticals with pass-through status effective on or after January 1, 2005, based on the MMA CY 2005 payment requirements for specified covered outpatient drugs. We have no ASP for Bexxar because it is a radiopharmaceutical, and manufacturers have not been required to submit ASP for radiopharmaceuticals. We have no claims data from which to calculate relative hospital costs for Bexxar because of the newness of the product. Therefore, we are setting payment for Bexxar in accordance with the MMA requirement that a sole source specified covered outpatient drug be paid no less than 83 percent of AWP in CY 2005.

Comment: A number of commenters, including several cancer centers and a nuclear medicine trade association, asked that CMS provide payment to hospitals for the cost of compounding each patient-specific dose of Bexxar, noting that the compounding costs amount to several thousand dollars in addition to the cost of the drug itself. One of these commenters recommended that the cost of compounding Bexxar be included in the payment for the product and that C1080 and C1081 be assigned to a new technology APC to reflect the total cost of the product plus compounding. One commenter, the manufacturer of Bexxar, is concerned because the payment proposed for Bexxar in CY 2005 does not include payment for the cost of compounding that is required to prepare patient specific doses of diagnostic and therapeutic I–131 tositumomab, whether done by the hospital's own radiopharmacy or by a commercial radiopharmacy. The commenter estimates that hospitals incur a compounding cost of $2,000–$3,000 to furnish Bexxar to a single patient when a commercial radiopharmacy does the compounding. The commenter recommends that CMS either base payment for Bexxar on 95 percent of AWP, continue payment for Bexxar at the CY 2004 level, or establish a new code to enable hospitals to bill separately for Bexxar compounding costs.

Response: Because Zevalin and Bexxar are radiopharmaceuticals that fall under the category of sole source specified covered drugs established by the MMA, the payment rates for these products are based on AWP, as required by the MMA. To the extent that compounding costs are reflected in the AWP, the payment rate includes these costs. If hospitals incur additional compounding costs for the radiolabeled monoclonal antibodies, those costs could be reported as a separate line item charge with an appropriate revenue code or packaged into the charge for CPT codes 78804 and 79403, which could result in an outlier payment if the outlier threshold for those services was exceeded. The MMA requires that MedPAC submit a report to the Secretary by July 1, 2005 on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. We look forward to receiving this report in anticipation that the data collected by MedPAC will enable us to address drug-related overhead costs in future OPPS updates.

Comment: Several commenters expressed concerns that the payment rates proposed for Bexxar could result in clinicians having to make treatment decisions based upon payment considerations rather than medical considerations, and could result in physicians having to deny patients a potential life-saving therapy. The same commenters were concerned that the payment proposed for Zevalin and Bexxar does not recognize all of the additional costs associated with the provision of radiolabeled antibody therapy or radioimmunotherapy (RIT) for the treatment of non-Hodgkins lymphoma. These commenters urged CMS to consider all of the costs associated with this therapy when setting payment rates for each component of the regimen and recommended that CMS ensure that total payment to hospitals be commensurate with all of the actual costs that hospitals incur to acquire, prepare, and administer radiolabeled antibodies and to perform all of the additional procedures associated with RIT, thereby ensuring that patient access to these vital therapies will not be jeopardized.

Response: We share the commenters' concerns about the extent to which payment considerations influence treatment decisions. However, we believe that to the extent that radioimmunotherapy proves to be an efficacious treatment for patients with certain forms of non-Hodgkins lymphoma, payment in the aggregate for the full array of procedures and services associated with this new form of treatment affords hospitals sufficient flexibility to ensure that payment is not a barrier to beneficiary access when it is deemed reasonable and necessary.

Table 26 below lists the final APC payment rates for sole source drugs, biologicals, and radiopharmaceuticals effective January 1, 2005 to December 31, 2005.

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Table 26. – CY 2005 APC Payment Rates for Sole Source Drugs, Biologicals, and Radiopharmaceuticals

HCPCS	Status Indicator	APC	Short Description	CY 2005 Payment Rate
A4642	K	0704	Satumomab pendetide per dose	$1,390.25
A9500	K	1600	Technetium TC 99m sestamibi	$106.32
A9502	K	0705	Technetium TC99M tetrofosmin	$104.58
A9504	K	1602	Technetium tc 99m apcitide	$415.00
A9507	K	1604	Indium/111 capromab pendetid	$1,915.23
A9508	K	1045	Iobenguane sulfate I-131, pe	$996.00
A9511	K	1095	Technetium TC 99m depreotide	$37.79
A9521	K	1096	Technetiumtc-99m exametazine	$778.13
A9605	K	0702	Samarium sm153 lexidronamm	$907.33
C1079	K	1079	CO 57/58 per 0.5 uCi	$221.78
C1080	K	1080	I-131 tositumomab, dx	$2,241.00
C1081	K	1081	I-131 tositumomab, tx	$19,422.00
C1082	K	9118	Indium111ibritumomabtiuxetan	$2,419.78
C1083	K	9117	Yttrium90ibritumomabtiuxetan	$20,948.25
C1091	K	1091	IN111 oxyquinoline,per0.5mCi	$373.50
C1092	K	1092	IN 111 pentetate per 0.5 mCi	$224.10
C1122	K	1122	Tc 99M ARCITUMOMAB PER VIAL	$1,079.00
C1178	K	1178	BUSULFAN IV, 6 Mg	$24.35
C1201	K	1201	TC 99M SUCCIMER, PER Vial	$118.52

HCPCS	Status Indicator	APC	Short Description	CY 2005 Payment Rate
C1305	K	1305	Apligraf	$1,130.88
C9003	K	9003	Palivizumab, per 50 mg	$576.51
C9008	K	9008	Baclofen Refill Kit-500mcg	$10.21
C9009	K	9009	Baclofen Refill Kit-2000mcg	$37.64
C9013	K	9013	Co 57 cobaltous chloride	$142.45
C9105	K	9105	Hep B imm glob, per 1 ml	$118.32
C9112	K	9112	Perflutren lipid micro, 2ml	$129.69
C9200	K	9200	Orcel, per 36 cm2	$991.85
C9201	K	9201	Dermagraft, per 37.5 sq cm	$529.54
C9202	K	9202	Octafluoropropane	$129.48
J0130	K	1605	Abciximab injection	$448.22
J0207	K	7000	Amifostine	$395.75
J0287	K	9024	Amphotericin b lipid complex	$19.09
J0288	K	0735	Ampho b cholesteryl sulfate	$15.20
J0289	K	0736	Amphotericin b liposome inj	$31.27
J0350	K	1606	Injection anistreplase 30 u	$2,353.53
J0583	K	9111	Inj, bivalirudin, 1 mg	$1.52
J0585	K	0902	Botulinum toxin a per unit	$4.32
J0587	K	9018	Botulinum toxin type B	$7.68
J0637	K	9019	Caspofungin acetate	$28.78
J0850	K	0903	Cytomegalovirus imm IV /vial	$622.13
J1260	K	0750	Dolasetron mesylate	$14.38
J1325	K	7003	Epoprostenol injection	$15.78
J1327	K	1607	Eptifibatide injection	$11.21
J1438	K	1608	Etanercept injection	$135.56
J1440	K	0728	Filgrastim 300 mcg injection	$162.41
J1441	K	7049	Filgrastim 480 mcg injection	$274.40
J1563	K	0905	IV immune globulin	$80.68
J1564	K	9021	Immune globulin 10 mg	$0.75
J1565	K	0906	RSV-ivig	$16.55
J1626	K	0764	Granisetron HCl injection	$16.20
J1745	K	7043	Infliximab injection	$57.40
J1830	K	0910	Interferon beta-1b / .25 MG	$58.73
J1950	K	0800	Leuprolide acetate /3.75 MG	$451.98
J2020	K	9001	Linezolid injection	$32.15
J2324	K	9114	Nesiritide	$132.47
J2353	K	1207	Octreotide injection, depot	$69.44
J2354	K	7031	Octreotide acetate injection, 25 mcg	$3.72
J2405	K	0768	Ondansetron hcl injection	$5.54
J2505	K	9119	Injection, pegfilgrastim	$2,448.50

HCPCS	Status Indicator	APC	Short Description	CY 2005 Payment Rate
J2788	K	9023	Rho d immune globulin 50 mcg	$30.38
J2792	K	1609	Rho(D) immune globulin h, sd	$17.95
J2820	K	0731	Sargramostim injection	$25.39
J2941	K	7034	Somatropin injection	$280.87
J2993	K	9005	Reteplase injection	$1,192.09
J3100	K	9002	Tenecteplase injection	$2,350.98
J3246	K	7041	Tirofiban hydrochloride	$8.24
J3305	K	7045	Inj trimetrexate glucoronate	$142.50
J3396	K	1203	Verteporfin injection	$8.49
J3487	K	9115	Zoledronic acid	$197.87
J7190	K	0925	Factor viii	$0.76
J7191	K	0926	Factor VIII (porcine)	$1.78
J7192	K	0927	Factor viii recombinant	$1.10
J7193	K	0931	Factor IX non-recombinant	$0.98
J7194	K	0928	Factor ix complex	$0.32
J7195	K	0932	Factor IX recombinant	$0.98
J7198	K	0929	Anti-inhibitor	$1.29
J7320	K	1611	Hylan G-F 20 injection	$203.70
J7504	K	0890	Lymphocyte immune globulin	$243.50
J7505	K	7038	Monoclonal antibodies	$747.31
J7507	K	0891	Tacrolimus oral per 1 MG	$3.05
J7511	K	9104	Antithymocyte globuln rabbit	$312.41
J7517	K	9015	Mycophenolate mofetil oral	$2.46
J7520	K	9020	Sirolimus, oral	$6.23
J8510	K	7015	Oral busulfan	$2.08
J8520	K	7042	Capecitabine, oral, 150 mg	$2.96
J8700	K	1086	Temozolomide	$6.42
J9001	K	7046	Doxorubicin hcl liposome inj	$343.78
J9020	K	0814	Asparaginase injection	$54.71
J9031	K	0809	Bcg live intravesical vac	$139.90
J9045	K	0811	Carboplatin injection	$129.96
J9151	K	0821	Daunorubicin citrate liposom	$56.44
J9170	K	0823	Docetaxel	$312.69
J9178	K	1167	EPIRUBICIN HCL, 2 mg	$24.14
J9185	K	0842	Fludarabine phosphate inj	$311.09
J9201	K	0828	Gemcitabine HCl	$105.73
J9202	K	0810	Goserelin acetate implant	$390.09
J9206	K	0830	Irinotecan injection	$127.33
J9213	K	0834	Interferon alfa-2a inj	$30.48
J9214	K	0836	Interferon alfa-2b inj	$13.00

HCPCS	Status Indicator	APC	Short Description	CY 2005 Payment Rate
J9215	K	0865	Interferon alfa-n3 inj	$8.17
J9217	K	9217	Leuprolide acetate suspnsion	$543.72
J9219	K	7051	Leuprolide acetate implant	$4,717.72
J9245	K	0840	Inj melphalan hydrochl 50 MG	$367.03
J9266	K	0843	Pegaspargase/singl dose vial	$1,247.08
J9268	K	0844	Pentostatin injection	$1,683.24
J9270	K	0860	Plicamycin (mithramycin) inj	$93.80
J9293	K	0864	Mitoxantrone hydrochl / 5 MG	$313.96
J9310	K	0849	Rituximab cancer treatment	$437.83
J9350	K	0852	Topotecan	$697.76
J9355	K	1613	Trastuzumab	$50.79
J9390	K	0855	Vinorelbine tartrate/10 mg	$95.23
J9600	K	0856	Porfimer sodium	$2,274.78
Q0136	K	0733	Non esrd epoetin alpha inj	$11.09
Q0137	K	0734	Darbepoetin alfa, 1 mcg[1]	$3.66
Q0166	K	0765	Granisetron HCl 1 mg oral	$39.04
Q0179	K	0769	Ondansetron HCl 8mg oral	$26.12
Q0180	K	0763	Dolasetron mesylate oral	$63.28
Q0187	K	1409	Factor viia recombinant	$1,410.34
Q2002	K	7022	Elliotts b solution per ml	$1.50
Q2003	K	7019	Aprotinin, 10,000 kiu	$12.51
Q2005	K	7024	Corticorelin ovine triflutat	$353.70
Q2006	K	7025	Digoxin immune fab (ovine)	$332.00
Q2007	K	7026	Ethanolamine oleate 100 mg	$63.29
Q2008	K	7027	Fomepizole, 15 mg	$10.04
Q2009	K	7028	Fosphenytoin, 50 mg	$5.31
Q2011	K	7030	Hemin, per 1 mg	$6.47
Q2013	K	7040	Pentastarch 10% solution	$131.99
Q2017	K	7035	Teniposide, 50 mg	$224.94
Q2018	K	7037	Urofollitropin, 75 iu	$56.59
Q2021	K	9057	Lepirudin	$130.30
Q2022	K	1618	VonWillebrandFactrCmplxperIU	$0.83
Q3000	K	9025	Rubidium-Rb-82	$153.39
Q3002	K	1619	Gallium ga 67	$27.10
Q3003	K	1620	Technetium tc99m bicisate	$370.60
Q3005	K	1622	Technetium tc99m mertiatide	$31.13
Q3007	K	1624	Sodium phosphate p32	$94.98
Q3008	K	1625	Indium 111-in pentetreotide	$1,079.00
Q3011	K	1628	Chromic phosphate p32	$147.25
Q3012	K	1089	Cyanocobalamin cobalt co57	$85.49
Q3025	K	9022	IM inj interferon beta 1-a	$74.44

[1] Equitable adjustment applied to payment rate

In order to determine the payment amounts for innovator multiple source and noninnovator multiple source forms of the drug, biological, or radiopharmaceutical, we compared the payments established under the median cost methodology to their reference AWP. For innovator multiple source items, we proposed to set payment rates at the lower of the payment rate calculated under our standard median cost methodology or 68 percent of the reference AWP. For noninnovator multiple source items, we proposed to set payment rates at the lower of the

payment rate calculated under our standard median cost methodology or 46 percent of the reference AWP. We followed this same methodology to set payment amounts for innovator multiple source and noninnovator multiple source ''specified covered outpatient drugs'' that were implemented by the January 6, 2004 interim final rule with comment period. We listed the proposed payment amounts in Table 26 of the proposed rule.

Comment: One commenter, an association of cancer centers, indicated that CMS proposed the same payment rate for both the brand name and generic versions of a drug. Given that CMS does not have separate HCPCS code level data for brand versus generic drugs in the CY 2003 claims data, the commenter indicated that it did not understand how CMS could use claims data to justify equivalent payment levels for both brand and generic versions of a drug. The commenter was also concerned about the adequacy of using the CY 2003 claims data to calculate the costs of these products and making comparisons to the payment rate ceilings set forth by the MMA for multi-source drugs, especially for the brand name drugs. Therefore, the commenter requested that CMS pay for all brand name drugs at 68 percent of AWP and pay for generics by comparing the calculated cost using the claims data to the 46 percent of AWP threshold and selecting the lower of the two as the payment rate.

Response: For CY 2005, as for the current year, the MMA sets forth different payment ceilings for the brand and generic versions of the drug. The MMA does not provide a payment floor for either the brand or generic versions of such items. Only sole source drugs have a payment floor and ceiling. As stated elsewhere in this final rule with comment period, the CY 2005 payment rate for innovator multiple source (brand name) drugs may not exceed 68 percent of the reference AWP. The payment for noninnovator multiple source (generic) drugs may not exceed 46 percent of the reference AWP. In determining payment rates, we apply those ceilings only when the payment for an item based on the median hospital cost for the drug exceeds one of these ceilings. In some cases, the payment based on the median hospital cost falls below the 46 percent ceiling for generic drugs. In such cases, the payment rate would be the same for brand and generic versions. However, we believe that basing payment for these items on relative hospital costs, with the application as appropriate of the previously mentioned ceilings not only meets the intent but also the requirements of the MMA.

Comment: A few commenters indicated that the proposed payment rate of $410.45 for HCPCS code A9600 (Supply of therapeutic radiopharmaceutical, Strontium-89, per mci) would underpay hospitals for this product since the payment rate was based on flawed CMS median cost data that do not accurately reflect the real acquisition cost of this drug by hospitals. The commenters believed that hospital costs for A9600 are approximately $800 per mci and requested that CMS adjust the payment accordingly. One commenter, who was the manufacturer of this product, asserted that the product is expensive and difficult to manufacture since it is produced in small quantities. The commenter also indicated that the reduction in the payment rate for this product is driving the underutilization of this product and increasing the use of costly narcotic analgesics, thus resulting in a decrease in quality of life and a rise in the cost of health care. Another commenter stated that the HCPCS codes for diagnostic and therapeutic iodine products (C1064, C1065, C1188, C1348, A9528, A9529, A9530, A9531, A9517 and A9518) all describe in various years and forms diagnostic and therapeutic Iodine 131 and that these codes have had varying descriptions that have resulted in flawed cost data. The commenter submitted data indicating that the cost for I–131 in the capsule form is higher than for solution, and recommended that CMS use external data to restore and correct payment rates for the Iodine 131 product so that the payment more accurately reflects actual hospital costs.

Response: We understand the commenters' concerns about establishing appropriate payment rates for these products. We believe that the intent of the statute is to use available hospital claims to set payment rates for most items paid under the OPPS. In the case of multiple source drugs such as these products, the MMA requires that innovator and noninnovator multiple source drugs be paid no more than 68 percent and 46 percent of their AWP, respectively.

As previously stated, for innovator multiple source drugs, we set the payment rate at the lower of the payment rate calculated under the standard median cost methodology or 68 percent of the AWP; and for noninnovator multiple source drugs, we set the payment rate at the lower of the payment rate calculated under the standard median cost methodology or 46 percent of the AWP. Using the most recent available data, we determined that the payment rates based on median cost for these drugs were lower than both 68 percent and 46 percent of their AWPs; therefore, the payment rates for both the innovator and noninnovator forms of these products were based on their median costs.

Comment: One commenter, the maker of one of the viscosupplement drugs, was concerned that the proposed payment rates for the four competitive products are inequitable and will harm beneficiary access to these therapies. The commenter indicated that currently two of the products, Hyalgan and Supartz, are billed using HCPCS code J7317 (Sodium Hyaluronate, per 20 to 25 mg dose for intra-articular injection), and this HCPCS code has been classified as a multi-source drug. The commenter assumed that another product, Orthovisc, would also be billed under HCPCS code J7317. However, the fourth product, Synvisc, is classified as a sole source drug and billed under HCPCS code J7320 (Hylan G–F20, 16 mg, for intra-articular injection). The commenter strongly believed that classifying these products differently resulted in payment rates that will create significant payment inequities and unjustified market distortions. To correct the payment inequity across the class of viscosupplements, the commenter recommended that CMS create separate HCPCS codes for these products and treat each product as a sole source drug. Another commenter strongly recommended that Orthovisc, a new product, be recognized as a pass-through under the OPPS, and be assigned a separate C-code for payments under that system.

Response: We recognize the commenter's concern about payment for these viscosupplement drugs under the OPPS. The National HCPCS Panel coordinates decisions regarding the creation of permanent HCPCS codes; therefore, comments related to the HCPCS creation process and decisions made by the National HCPCS Panel are outside the scope of this rule. However, we note that the product Orthovisc received approval for pass-through status under the OPPS effective January 1, 2005, and a new temporary C-code has been established to allow hospitals to receive pass-through payments for this product.

Comment: A commenter requested that CMS show three separate tables for the nonpass-through drugs; that is, one for sole source drugs, one for innovator multiple source drugs, and one for noninnovator multiple source drugs.

Response: We have accepted the commenter's suggestion and created three distinct tables listing the sole source drugs, innovator multiple sources drugs, and noninnovator multiple source drugs.

Tables 27 and 28 below list the final payment amounts for innovator and noninnovator multiple source drugs, biologicals, and radiopharmaceuticals, respectively, effective January 1, 2005 to December 31, 2005.

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Table 27. – CY 2005 APC Payment Rates for Multiple Source Innovator Drugs, Biologicals, and Radiopharmaceuticals

HCPCS	Status Indicator	APC	Short Description	CY 2005 Payment Rate
C1775	K	1775	FDG, per dose (4-40 mCi/ml)	$221.11
C9400	K	9400	Thallous chloride, brand	$21.19
C9401	K	9401	Strontium-89 chloride, brand	$406.16
C9402	K	9402	Th I131 so iodide cap, brand	$6.57
C9403	K	9403	Dx I131 so iodide cap, brand	$6.57
C9404	K	9404	Dx I131 so iodide sol, brand	$9.73
C9405	K	9405	Th I131 so iodide sol, brand	$9.73
C9410	K	9410	Dexrazoxane HCl inj, brand	$123.93
C9411	K	9411	Pamidronate disodium, brand	$160.65
C9413	K	9413	Sodium hyaluronate inj, brand	$53.94
C9414	K	9414	Etoposide oral, brand	$25.71
C9415	K	9415	Doxorubic hcl chemo, brand	$6.94
C9417	K	9417	Bleomycin sulfate inj, brand	$130.56
C9418	K	9418	Cisplatin inj, brand	$11.42
C9419	K	9419	Inj cladribine, brand	$36.72
C9420	K	9420	Cyclophosphamide inj, brand	$4.10
C9421	K	9421	Cyclophosphamide lyo, brand	$3.50
C9422	K	9422	Cytarabine hcl inj, brand	$2.28
C9423	K	9423	Dacarbazine inj, brand	$8.15
C9424	K	9424	Daunorubicin, brand	$53.14
C9425	K	9425	Etoposide inj, brand	$1.22
C9426	K	9426	Floxuridine inj, brand	$97.92
C9427	K	9427	Ifosfomide inj, brand	$90.80
C9428	K	9428	Mesna injection, brand	$23.79
C9429	K	9429	Idarubicin hcl inj, brand	$66.58
C9430	K	9430	Leuprolide acetate inj, brand	$21.41
C9431	K	9431	Paclitaxel inj, brand	$93.50
C9432	K	9432	Mitomycin inj, brand	$45.70
C9433	K	9433	Thiotepa inj, brand	$66.98
C9435	K	9435	Gonadorelin hydroch, brand	$17.08
C9436	K	9436	Azathioprine parenteral,brnd	$44.61
C9437	K	9437	Carmus bischl nitro inj	$79.42
C9438	K	9438	Cyclosporine oral, brand	$1.78
C9439	K	9439	Diethylstilbestrol injection	$10.32

Table 28. – CY 2005 Payment Amounts for Noninnovator Multiple Source Drugs, Biologicals, and Radiopharmaceuticals

HCPCS	Status Indicator	APC	Short Description	CY 2005 Payment Rate
A9505	K	1603	Thallous chloride TL 201/mci	$18.29
A9517	K	1064	Th I131 so iodide cap millic	$6.57
A9528	K	1064	Dx I131 so iodide cap millic	$6.57
A9529	K	1065	Dx I131 so iodide sol millic	$9.73
A9530	K	1065	Th I131 so iodide sol millic	$9.73
A9600	K	0701	Strontium-89 chloride	$406.16
J1190	K	0726	Dexrazoxane HCl injection	$113.28
J1620	K	7005	Gonadorelin hydroch/ 100 mcg	$17.08
J2430	K	0730	Pamidronate disodium /30 MG	$128.74
J7317	K	7316	Sodium hyaluronate injection	$53.94
J7501	K	0887	Azathioprine parenteral	$30.18
J7502	K	0888	Cyclosporine oral 100 mg	$1.78
J8560	K	0802	Etoposide oral 50 MG	$21.91
J9000	K	0847	Doxorubic hcl 10 MG vl chemo	$4.69
J9040	K	0857	Bleomycin sulfate injection	$88.32
J9050	K	0812	Carmus bischl nitro inj	$65.94
J9060	K	0813	Cisplatin 10 MG injection	$7.73
J9065	K	0858	Inj cladribine per 1 MG	$24.84
J9070	K	0815	Cyclophosphamide 100 MG inj	$2.77
J9093	K	0816	Cyclophosphamide lyophilized	$2.36
J9100	K	0817	Cytarabine hcl 100 MG inj	$1.55
J9130	K	0819	Dacarbazine 100 mg inj	$6.14
J9150	K	0820	Daunorubicin	$35.94
J9165	K	0822	Diethylstilbestrol injection	$6.98
J9181	K	0824	Etoposide 10 MG inj	$0.83
J9200	K	0827	Floxuridine injection	$66.24
J9208	K	0831	Ifosfomide injection	$72.81
J9209	K	0732	Mesna injection	$17.66
J9211	K	0832	Idarubicin hcl injection	$66.58
J9218	K	0861	Leuprolide acetate injeciton	$14.48
J9265	K	0863	Paclitaxel injection	$79.04
J9280	K	0862	Mitomycin 5 MG inj	$30.91
J9340	K	0851	Thiotepa injection	$45.31

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b. Treatment of Three Sunsetting Pass-Through Drugs as Specified Covered Outpatient Drugs

As we discussed in the August 16, 2004 proposed rule, there are 13 drugs and biologicals whose pass-through status will expire on December 31, 2004. Table 29 below lists these drugs and biologicals.

Pass-through payment was made for 10 of these 13 items as of December 31, 2002. Therefore, these 10 items now qualify as specified covered outpatient drugs under section 1833(t)(14) of the Act, as added by section 621(a) of Pub. L. 108–173, as described above. However, pass-through status for three of the pass-through drugs and biologicals that will expire on December 31, 2004 (C9121, Injection, Argatroban; J9395, Fulvestrant; and J3315, Triptorelin pamoate), was first made effective on January 1, 2003. These items are specifically excluded from the definition of ''specified covered outpatient drugs'' in section 1833(t)(14)(B)(ii) of the Act, because they are not drugs or biologicals for which pass-through payment was first made on or before December 31, 2002. Pub. L. 108–173 does not address how

to set payment for items whose pass-through status expires in CY 2004, but for which pass-through payment was not made as of December 31, 2002.

Therefore, we proposed to pay for the three expiring pass-through items for which payment was first made on January 1, 2003, rather than on or before December 31, 2002 using the methodology described under section 1833(t)(14) of the Act for specified covered outpatient drugs. We believed that this methodology would allow us to determine appropriate payment amounts for these products in a manner that is consistent with how we pay for drugs and biologicals whose pass-through status was effective as of December 31, 2002, and that does not penalize those products for receiving pass-through status beginning on or after January 1, 2003 and expiring December 31, 2004. In Table 27 in the proposed rule, we listed the CY 2005 OPPS payment rates that we proposed for these three drugs and biologicals.

Of the 13 products for which we proposed that pass-through status expire on December 31, 2004, we proposed to package two of them (C9113, Inj. Pantoprazole sodium and J1335, Ertapenum sodium) because their median cost per day falls below the $50 packaging threshold. We proposed to pay for the remaining 11 drugs and biologicals as sole source items according to the payment methodology for sole source products described above.

We note that darbepoetin alfa (Q0137) will be considered a ''specified covered outpatient drug'' in CY 2005. Payment for these drugs is governed under section 1833(t)(14) of the Act. Specifically, we proposed that darbepoetin alfa would be paid as a sole source drug at a rate between 83 percent and 95 percent of its reference AWP. Accordingly, we specifically solicited comments on whether we should again apply an equitable adjustment, made pursurant to section 1833(t)(2)(E) of the Act, to the price for this drug.

Comment: Numerous commenters applauded CMS for proposing a fair and consistent payment methodology for drugs and biologicals whose pass-through status expires on December 31, 2004, and supported the proposal to treat these three therapies as specified covered outpatient drugs. They also encouraged CMS to expand this treatment to all separately paid drugs and biologicals in the future. A few commenters, including MedPAC, disagreed with our proposal to pay for the three expiring pass-through items for which payment was first made on January 1, 2003, as ''specified covered outpatient drugs.'' One commenter indicated that because these three drugs were excluded from the statutory definition of ''specified covered outpatient drug,'' it did not believe that CMS had the authority to treat newer drugs expiring out of pass-through status as specified covered outpatient drugs. Therefore, the commenter believed that CMS should pay for newer drugs expiring from pass-through status at 106 percent ASP, the rate applicable to the physician setting. MedPAC expressed concern about treating these 3 expiring pass-through drugs differently from the older, historically packaged drugs that are now eligible for separate payment and whose payments will be based on the median cost from the claims data. MedPAC indicated that the purpose of the pass-through payments is to allow time to accumulate data on costs and that there seemed to be no reason to believe that claims data are more accurate for one category of drugs that the other. Therefore, the drugs coming off pass-through, which do not fall under the SCOD category, and the older drugs should be paid consistently.

Response: We appreciate the commenters' support for our proposal to treat the three items for which pass-through status expires on December 31, 2004, but that were approved for pass-through status effective January 1, 2003, similar to the other drugs and biologicals whose pass-through status expires December 31, 2004, but that were approved for pass-through status on or before December 31, 2002. The statute does not address payment for drugs and biologicals that had pass-through status effective on January 1, 2003, but not on or before December 31, 2002. These items are newer drugs than the older products that never received pass-through status. We have accumulated cost data for these three drugs throughout the same 2-year period during which we accumulated cost data for the other drugs and biologicals whose pass-through status expires on December 31, 2004. Therefore, noting that the statute does not address drugs whose pass-through status likewise expires on December 31, 2004, but was approved on January 1, 2003, we believe it is reasonable to pay for these three drugs in a manner consistent with how we pay for the other drugs whose pass-through status likewise sunsets on December 31, 2004.

Comment: We received a number of comments concerning our proposal to pay for both epoetin alfa (marketed under trade name of Procrit) and darbepoetin alfa (marketed under the trade name of Aranesp®) based on 83 percent of their individual reference AWPs. A number of commenters also wrote in response to our solicitation for comments concerning the application of our equitable adjustment authority in determining the payment rate for darbepoetin alfa. Commenters acknowledged that both biologicals meet the MMA definition of specified covered outpatient drug (SCOD) and that the pass-through status of darbepoetin alfa ends on January 1, 2005. One of the commenters supported the proposal to establish payment for darbepoetin alfa as a SCOD, to base CY 2005 payment on its reference AWP, and to discontinue the application of an equitable adjustment to reduce the statutorily mandated payment for any product paid under the OPPS in CY 2005. This commenter stated the proposed payment for darbepoetin alfa as a sole source SCOD is fully consistent with section 621 of the MMA and that this is consistent with the method of payment for all other sole source SCODs. The commenter further stated that when drafting the language for section 622 of the MMA, Congress intended to ensure that considerations of functional equivalence were not applied to darbepoetin alfa after its pass-through status expired. This commenter acknowledges that section 1833(t)(2)(E) of the Act permits CMS to make ''adjustments as determined to be necessary to ensure equitable payments.'' However, this commenter stated that payments for the two products are already inherently equitable at the proposed rates because they are comparably priced and because CMS proposed to set the payment rates for the two products using the same methodology. The commenter noted that when CMS first applied the equitable adjustment for darbepoetin alfa, in CY 2003, CMS had only three choices for establishing drug payments under the OPPS: (1) Packing payment with related services; (2) using charges from outpatient claims to derive median cost; and (3) paying separately under the pass-through provisions, at 95 percent of AWP. The commenter notes the new payment methodology for all sole source ''specified covered outpatient drugs'' and argues that by applying this methodology to both of these biologicals, CMS would establish a level playing field and assure that market-based forces remain operable. This commenter also provided data concerning the clinical efficacy of darbepoetin alfa.

Many of the other commenters stated that CMS' application of its equitable adjustment authority deviated from the MMA's intent to pay for sole source

products and multi-source products under separate payment methodologies. The commenters were concerned about the significant impact that application of such authority may have on a company's decision to continue developing innovator products. The commenters also argued that applying such a policy could inject CMS into clinical decisions based solely on economic considerations and create payment incentives that distort patient decisions properly entrusted to treating physicians. One commenter recommended that if CMS plans to utilize this authority again, then CMS should hold a public forum and provide interested parties with an opportunity to submit written comments about the standards that will be used to determine equitable adjustment. Other commenters argued that CMS should comply with the MMA and protect patient access to innovative therapies by not applying functional equivalence or a similar standard to any drug in 2005 or future years.

One commenter on this topic also provided detailed results of clinical studies that the commenter believes support the necessity of a continuation of the equitable payment adjustment. This commenter further stated that the clinical data support the use of a particular conversion ratio in making such an adjustment. The commenter noted that without an equitable adjustment policy, both drugs would be paid at 83 percent of each product's AWP. The commenter estimated weekly payments for the two drugs under four scenarios: an equitable adjustment based on three different conversion ratios and the proposed policy of treating each drug independently without application of an equitable adjustment. According to this commenter, overall Medicare expenditures and beneficiary coinsurance payments would increase for the treatment of chemotherapy-induced anemia in the absence of an equitable payment adjustment. The commenter's estimates assume a 50 percent market share for each of the two drugs and estimated 2005 spending based on 2003 OPPS claims data with anemia market unit growth assumptions of 35 percent in 2004 and 22 percent in 2005. The commenter also noted that the MMA did not remove the Secretary's authority to establish adjustments to ensure equitable payments and that the Secretary retains the authority to determine the CY 2005 payment rate for darbepoetin alfa using the equitable payment policy applied in CY 2003 and CY 2004. This commenter also argued that the MMA prohibition on the use of a functional equivalence standard applies only to pass-through drugs and only to future implementation.

A comment from MedPAC on this issue indicated that as costs to the Medicare program continue to grow, the program will need to examine tools for obtaining value in its purchasing. MedPAC believed that, absent evidence that the CMS' use of its equitable adjustment to set equivalent payment rates for Procrit and Aranesp® denied beneficiaries' access to needed treatments, CMS should pursue value-based purchasing where possible.

Response: As the commenters noted, while we proposed a payment rate for darbepoetin alfa as a sole source SCOD based on its reference AWP, we also specifically solicited comments on whether we should again apply an equitable adjustment, made pursuant to section 1833(t)(2)(E) of the Act, to establish the payment for this drug in CY 2005. After careful consideration of the thoughtful and well-documented comments concerning this issue, we have concluded that it is still appropriate to apply an adjustment to the payment for darbepoetin alfa under our authority in section 1833(t)(2)(E) of the Act to ensure that equitable payments for these two products under the OPPS continue in CY 2005. We agree with those commenters that argued that section 1833(t)(2)(E) of the Act was not affected by the provisions of the MMA and that we retain our authority to make such adjustments to payments under the OPPS. As we have done previously, we will reassess the need to exercise our adjustment authority when we next review the payment rates under the OPPS.

To apply an equitable adjustment for CY 2005, we reviewed the analysis we conducted during 2003 and the additional data we received in 2004. As we discussed in further detail in our November 7, 2003 final rule with comment period for the 2004 update to the OPPS (68 FR 63455) and our November 1, 2002 final rule with comment period for the 2003 update (67 FR 66758), because darbepoetin alfa has two additional carbohydrate side-chains, it is not structurally identical to epoetin alfa. The addition of these two carbohydrate chains affects the biologic half-life of the compound. This change in turn affects how often the biological can be administered, which yields a different dosing schedule for darbepoetin alfa by comparison to epoetin alfa. Amgen has FDA approval to market darbepoetin alfa under the trade name ® for treatment of anemia related to chronic renal failure (including patients on and not on dialysis) and for treatment of chemotherapy-related anemia in cancer patients. Epoetin alfa, which is marketed by Ortho Biotech under the trade name Procrit, is approved by FDA for marketing for the following conditions: (1) Treatment of anemia of chronic renal failure (including for patients on and not on dialysis); (2) treatment of Zidovudine-related anemia in HIV patients; (3) treatment of anemia in cancer patients on chemotherapy; and (4) treatment of anemia related to allogenic blood transfusions in surgery patients.

The two biologicals are dosed in different units. Epoetin alfa is dosed in Units per kilogram (U/kg) of patient weight and darbepoetin alfa in micrograms per kilogram (mcg/kg). The difference in dosing metric is due to differences in the accepted convention at the time of each product's development. At the time epoetin alfa was developed, biologicals (such as those like epoetin alfa that are produced by recombinant DNA technology) were typically dosed in International Units (or Units for short), a measure of the product's biologic activity. They were not dosed by weight (for example, micrograms) because of a concern that weight might not accurately reflect their standard biologic activity. The biologic activity of such products can now be accurately predicted by weight, however, and manufacturers have begun specifying the doses of such biologicals by weight. No standard formula exists for converting amounts of a biologic dosed in Units to amounts of drug dosed by weight.

The process that we used in 2003 to define the payment conversion ratio between the two biologicals for CY 2004 is described in the November 7, 2003 final rule with comment period. We refer readers to that discussion, found at 68 FR 63455, for more complete details on that process and the data received and reviewed by CMS during the process. At the conclusion of the 2003 process, we established a conversion ratio of 330 Units of epoetin alfa to 1 microgram of darbepoetin alfa (330:1) for establishing the CY 2004 payment rate for darbepoetin alfa.

During the comment period, each company presented additional data concerning their products. Based upon our analysis to date, we continue to believe that the conversion ratio used for CY 2004 is appropriate for purposes of establishing equitable payment under the OPPS for both epoetin alfa and darbepoetin alfa for CY 2005. Initial review of new information submitted by the commenters provides no compelling

evidence that the conversion ratio of 330:1 is unreasonable. Therefore, for this final rule with comment period, we have established payment for darbepoetin alfa by applying the conversion ratio of 330:1 to 83 percent of the AWP for epoetin alfa. The resulting payment rate for darbepoetin alfa is $3.66 per microgram. We will continue to assess the data we have received thus far and invite the submission of additional information. In order to fully evaluate and assess this issue in determining whether any further adjustment of the conversion ratio is necessary, additional analysis will be required. If, after additional review and analysis, we determine that a different conversion ratio is more appropriate, we will make a change in the payment rate for darbepoetin alfa to reflect the change in ratio as soon as possible.

We do not believe that our application of an equitable adjustment will create a barrier to treatment for the conditions for which these products are prescribed or to the product of choice of the beneficiary and his or her treating physician. According to the most recent average sales price (ASP) information collected by CMS and available in time for this final rule with comment period, 106 percent of ASP for darbepoetin alfa is $3.69 per microgram. This amount would have been the basis for payment under the OPPS on January 1, 2005 if pass-through status did not expire and if we did not apply an equitable adjustment. Furthermore, as we have emphasized in prior rulemaking on this topic, our conversion of amounts of a biologic dosed in Units to amounts of a drug dosed by weight strictly for the purpose of calculating a payment rate should not in any way be viewed as a statement regarding the clinical use of either product. The method we use to convert Units to micrograms in order to establish equitable payments is not intended to serve as a guide for dosing individual patients in clinical practice. By using a conversion ratio solely for the purpose of establishing equitable payments, CMS is not attempting to establish a lower or upper limit on the amount of either biological that a physician should prescribe to a patient. We expect that physicians will continue to prescribe these biologicals based on their own clinical judgment of the needs of individual patients.

Table 29 below lists the final CY 2005 OPPS payment rates for the three sunsetting pass-through drugs and biologicals that will be treated as specified covered outpatient drugs.

Table 29. -- CY 2005 APC Payment Rates for Three Expiring Pass-Through Drugs and Biologicals That Will Be Treated As Specified Covered Outpatient Drugs

HCPCS Code	Status Indicator	Short Description	APC	CY 2005 Payment Rate
J9395	K	Injection, Fulvestrant	9120	$79.65
J3315	K	Triptorelin pamoate	9122	$362.78
C9121	K	Injection, argatroban	9121	$12.45

c. CY 2005 Payment for Nonpass-through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes, But Without the OPPS Hospital Claims Data

Pub. L. 108–173 does not address the OPPS payment in CY 2005 for new drugs and biologicals that have assigned HCPCS codes, but that do not have a reference AWP or approval for payment as pass-through drugs or biologicals. Because there is no statutory provision that dictates payment for such drugs and biologicals in CY 2005, and because we have no hospital claims data to use in establishing a payment rate for them, we investigated other possible options to pay for these items in CY 2005. Clearly, one option is to continue packaging payment for these new drugs and biologicals that have their own HCPCS codes until we accumulate sufficient claims data to calculate median costs for these items. Another option is to pay for them separately using a data source other than our claims data. The first option is consistent with the approach we have taken in prior years when claims data for new services and items have not been available to calculate median costs. However, because these new drugs and biologicals may be expensive, we are concerned that packaging these new drugs and biologicals may jeopardize beneficiary access to them. In addition, we do not want to delay separate payment for a new drug or biological solely because a pass-through application was not submitted.

Therefore, for CY 2005, we proposed to pay for these new drugs and biologicals with HCPCS codes but which do not have pass-through status at a rate that is equivalent to the payment they would receive in the physician office setting, which would be established in accordance with the methodology described in the CY 2005 Medicare Physician Fee Schedule proposed rule (69 FR 47488, 47520 through 47524). We noted that this payment methodology is the same as the methodology that will be used to calculate the OPPS payment amount that pass-through drugs and biologicals will be paid in CY 2005 in accordance with section 1842(o) of the Act, as amended by section 303(b) of Pub. L. 108–173, and section 1847A of the Act. Thus, we proposed to treat new drugs and biologicals with established HCPCS codes the same, irrespective of whether pass-through status has been determined. We also proposed to assign status indicator ''K'' to HCPCS codes for new drugs and biologicals for which we have not received a pass-through application.

In light of our August 16, 2004 proposal, we understood that manufacturers might be hesitant to apply for pass-through status. However, we did not believe there would be many instances in CY 2005 when we would not receive a pass-through application for a new drug or biological that has an HCPCS code. To avoid delays in setting an appropriate payment amount for new drugs and biologicals and to expedite the processing of claims, we strongly encouraged manufacturers to continue submitting pass-through applications for new drugs and biologicals when FDA

approval for a new drug or biological is imminent to give us advance notice to begin working to create an HCPCS code and APC. The preliminary application would have to be augmented by FDA approval documents and final package inserts once such materials become available. However, initiating the pass-through application process as early as possible would enable us to expedite coding and pricing for the new drugs and biologicals and accelerate the process for including them in the next available OPPS quarterly release.

In the August 16, 2004 proposed rule, we discussed how we proposed to pay in CY 2005 for new drugs and biologicals between their FDA approval date and assignment of an HCPCS code and APC. We shared the desire of providers and manufacturers to incorporate payment for new drugs and biologicals into the OPPS as expeditiously as possible to eliminate potential barriers to beneficiary access and to minimize the number of claims that must be processed manually under the OPPS interim process for claims without established HCPCS codes and APCs, and we solicited public comments on our proposal.

Comment: Several commenters commended CMS's proposal to set payment rates for new drugs with HCPCS codes using the same methodology proposed to set payment for drugs with pass-through status, regardless of whether a pass-through application has been submitted for the new drug. They applauded CMS for acknowledging that packaging payment for these new therapies might jeopardize beneficiary access to them. However, a comment from MedPAC indicated that CMS's proposal to pay 106 percent of ASP for this particular group of drugs and biologicals represented a change in policy where drugs of this nature were previously packaged until sufficient claims data were accumulated to calculate payment rates, unless they received pass-through status via an application process. MedPAC was concerned that the newly approved drugs and biologicals that do not go through the pass-through payment mechanism will be added to the OPPS system without any control on spending since this policy does not have a budget neutrality provision, similar to pass-through payments. Given that the pass-through policy existed as a controlled mechanism for introducing new drugs into the OPPS, these drugs should either be treated through the pass-through process or continue to be packaged under the previous policy.

Response: We appreciate the commenters' support for our proposal to pay for new drugs with HCPCS codes, but without pass-through status and hospital claims data under the same methodology that will be used to pay for them in the physician office setting. We also understand MedPAC's concern about budget neutrality associated with this policy. Our intent in paying for new drugs and biologicals with HCPCS codes, but without pass-through status and hospital claims data, separately, was that we recognized that some of these new products would be important new therapies in treatment of such diseases as cancer. We also believe that the MMA provision that requires CMS to pay for new drugs and biologicals before a code is assigned indicates that Congress intended for us to pay separately for new items until we have hospital claims data that would allow us to determine whether the product should be packaged. We are concerned that packaging their payments may prevent hospitals from acquiring these products and in turn harm beneficiaries' access to them. We do not expect the volume of new drugs and biologicals to which we would apply this policy in CY 2005 to be so significant as to have an effect on budget neutrality. Moreover, we would not expect this policy to have a differential impact on budget neutrality any more than payment for the drugs would affect pass-through spending had the drugs been approved for pass-through status. We also believe (and strongly encourage) that stakeholders will continue to apply for pass-through status for new drugs, biologicals and radiopharmaceuticals as a means of ensuring that we have all of the information required to establish accurate payments for these items as quickly as possible. At the same time, if we were to package all such items, we are concerned that it would provide a disincentive for manufacturers to come forward and request codes for new items. Under the MMA provision described above, we are required to pay for new drugs and biologicals without HCPCS code at 95 percent of AWP, which we would expect to generally be higher than 106 percent of ASP. We also believe the MMA provision regarding drugs without HCPCS codes indicates that Congress clearly intended that we pay separately for new drugs and biologicals. Therefore, for CY 2005 we will finalize the policy that we proposed to pay separately for new drugs and biologicals with HCPCS codes but without pass-through status and hospital claims data based on the payment for the same new products in a physician office.

We will, however, monitor this carefully during the course of CY 2005 and reassess the policy for CY 2006. In CY 2005, payment for these new drugs and biologicals will be based on 106 percent of ASP. In the absence of ASP data, we will use wholesale acquisition cost (WAC) for the product to establish the initial payment rate. If WAC is also unavailable, then we will calculate payment at 95 percent of the May 1, 2003 AWP or the first reported AWP for the product. We have used the second quarter ASP data from CY 2004 because those were the most recent numbers available to us in time for the publication for this rule. To be consistent with the ASP-based payments that will be made when these drugs and biologicals are furnished in the physician offices, we plan to make any appropriate adjustments to the amounts shown in Addendum A and B if later quarter ASP submissions indicate that adjustments to the payment rates are necessary. We will announce such changes in our program instructions to implement quarterly releases and post any revisions to the addenda on the *www.cms.hhs.gov* Web site. We will similarly adjust payment for items for which we used AWP or WAC because ASP was not available if ASP becomes available from later quarter submissions.

For CY 2005, we will apply this policy to three drugs and biologicals that are new effective January 1, 2005 and do not have pass-through status and hospital claims data. These drugs will be separately payable under the OPPS, and thus, we have assigned them to status indicator ''K''. Table 30 below lists these drugs and biologicals and the payment methodologies used to calculate their APC payments listed in Addendum A and B of this rule.

Table 30. -- New CY 2005 HCPCS Codes for Drugs and Biologicals without Pass-Through Status and Hospital Claims Data

HCPCS Code	APC	Short Descriptor	CY 2005 Payment Methodology
J0135	1083	Injection, Adalimumab, 20 mg	95% AWP
J1457	1085	Injection, Gallium nitrate, 1 mg	WAC
J7674	0867	Methacholine Chloride, neb	95% AWP

We have also identified several drugs and biologicals with new HCPCS codes created effective January 1, 2004, that do not meet the definition of ''specified covered outpatient drugs'' and for which we would not have CY 2003 hospital claims data. These items are packaged in CY 2004, and we also proposed to package them for CY 2005 in the proposed rule. To avoid negatively impacting beneficiary access to these new products by packaging them, we will be paying for these drugs in CY 2005 under the same methodology that will be used to pay for them in the physician office setting. The rules for determining payment for these drugs will be the same as the rules for new drugs with HCPCS codes but without pass-through status in CY 2005. In CY 2005, these drugs will be separately payable under the OPPS, and thus, we have assigned status indicator ''K'' to these drugs. Table 31 below lists these drugs and biologicals and the payment methodologies used to calculate their APC payments listed in Addendum A and B of this rule.

We note that CPT 90715 (Tdap vaccine > 7 im) was newly created in 2004; however, we will not apply this payment policy to this code because all of the vaccines similar to this product are packaged in CY 2004 and will remain packaged in CY 2005. This payment policy also will not apply to new radiopharmaceuticals since all radiopharmaceuticals meet the definition of ''specified covered outpatient drugs''. Therefore, payment for new radiopharmaceuticals will be made according to the payment methodologies established for ''specified covered outpatient drugs'' under section 1833(t)(14)(A)(ii) of the Act.

Table 31. - New 2004 HCPCS Codes for Drugs and Biologicals without Pass-Through Status and Hospital Claims Data

HCPCS	APC	Description	CY 2005 Payment Methodology
J0595	0703	Butorphanol tartrate 1 mg	106 % ASP
J2185	0729	Meropenem	106% ASP
J2280	1046	Inj, moxifloxacin 100 mg	WAC
J3411	1049	Thiamine hcl 100 mg	WAC
J3415	1050	Pyridoxine hcl 100 mg	WAC
J3465	1052	Injection, voriconazole	106% ASP
Q4075	1062	Acyclovir, 5 mg	106% ASP
Q4076	1070	Dopamine hcl, 40 mg	106% ASP
Q4077	1082	Treprostinil, 1 mg	106% ASP

Comment: One commenter noted that CMS historically had declined to process pass-through applications prior to FDA approval, consequently many manufacturers have ceased submitting early applications. The commenter stated that manufacturers may be uncomfortable submitting the detailed information required for the pass-through application prior to securing FDA approval. The commenter suggested that a more realistic expectation of the timeframe for pass-through application would be at or subsequent to FDA approval, when the product launch is imminent.

Response: We recognize that some manufacturers may be concerned about submitting detailed information for pass-through application in advance of FDA's approval for their product. However, we reiterate that we strongly encourage manufacturers to continue submitting pass-through applications when FDA approval for a new drug or biological is imminent to give us advance notice to begin working to create a HCPCS code and an APC for their product. While we will not be able to give final approval to the pass-through application prior to FDA approval, early notification about the product prior to FDA approval can expedite the granting of a new product-specific code and implementation of

that code and appropriate payment rate within our system.

d. Payment for Separately Payable NonPass-Through Drugs and Biologicals

As discussed in section V.B.2. of the August 16, 2004 proposed rule, for CY 2005, we used CY 2003 claims data to calculate the proposed median cost per day for drugs, biologicals, and radiopharmaceuticals that have an assigned HCPCS code and are paid either as a packaged or separately payable item under the OPPS. Section 1833(t)(14) of the Act, as added by section 621(a) of Pub. L. 108–173, specified payment methodologies for most of these drugs, biologicals, and radiopharmaceuticals. However, this provision did not specify how payment was to be made for separately payable drugs and biologicals that never received pass-through status and that are not otherwise addressed in section 1833(t)(14) of the Act. Some of the items for which such payment is not specified are (1) those that have been paid separately since implementation of the OPPS on August 1, 2000, but are not eligible for pass-through status, and (2) those that have historically been packaged with the procedure with which they are billed but, based on the CY 2003 claims data, their median cost per day is above the legislated $50 packaging threshold. Because Pub. L. 108–173 does not address how we are to pay for such drugs and biologicals (any drug or biological that falls into one or the other category and that has a per day cost greater than $50), we proposed to set payment based on median costs derived from the CY 2003 claims data. Because these products are generally older or low-cost items, or both, we believe that the payments will allow us to provide adequate payment to hospitals for furnishing these items. In the proposed rule, we listed in Table 28 the drugs and biologicals to which the proposed payment policy would apply.

We received numerous public comments on our proposal.

Comment: A commenter expressed concern about the proposed payment rate for HCPCS code J7342 (Dermal tissue, of human origin, with or without other bio-engineered or processed elements, with metabolically active elements, per square centimeter) when billed by Maryland-based hospitals and comprehensive outpatient rehabilitation facilities (CORFs).

Response: We understand the commenter's concern; however, Maryland-based hospitals and CORFs are excluded from payment under the OPPS and the OPPS payment rates do not apply to them. This final rule with comment period addresses only the providers that are paid under the OPPS. Therefore, this comment is outside the scope of this rule.

Comment: An association for manufacturers of contrast agents supported CMS' proposal to pay separately for certain MRI contrast agents (for example, HCPCS codes A4643 and A4647). However, the commenter was concerned that the payment rates for these products were based on CY 2003 hospital claims data and that the overall accuracy of the hospital median cost data is questionable; therefore, the commenter recommended that CMS review the proposed payment rates for MRI contrast agents and requested that such review include a confirmation that the median cost data used as the basis for calculating the payment rates are correct. The commenter also indicated that the proposed rule did not have unit descriptors for the HCPCS codes A4643 and A4647 and requested that CMS add the unit descriptor, ''up to 20 ml'' to HCPCS codes A4643 and A4647 in order to provide further clarity and facilitate more accurate coding and billing by hospitals.

Response: We understand the commenter's concern about setting appropriate payment rates for these products. These products do not meet the definition of ''specified covered outpatient drugs'' as defined in the MMA; however, we do have a significant number of CY 2003 hospital claims data for these products. It is our general policy under the OPPS to use the most recent available hospital claims data in setting the OPPS payment rates. For CY 2005, both of these products will be separately payable items. The payment rate for A4643 will be based on approximately 14,200 claims for approximately 27,000 services, and payment for A4647 will be based on approximately 87,600 claims for approximately 155,000 services.

We believe that the CY 2003 claims data contain a sufficiently robust set of claims for both products on which to base the payment rates for these items using the methodology that will be used for other separately payable non-pass-through drugs and biologicals. With respect to adding unit descriptors to A4643 and A4647, we suggest that the commenter pursue these changes through the process set up by the National HCPCS Panel.

Comment: A commenter expressed concern that CMS may have inappropriately packaged low osmolar contrast material (LOCM) drugs into APCs based on a determination that the drugs do not meet CMS's packaging rule because they are below the $50 threshold required for separate payment. The commenter questioned the accuracy of the median cost data used as the basis for CMS's decision as CMS' paid claims files for LOCM do not include unit descriptors for the HCPCS codes A4644, A4645, and A4646. The commenter is concerned that this makes it difficult to interpret the data in any meaningful way for purposes of determining what the payment rates for these drugs should be and whether they should be paid separately, in particular, because the dose administered per procedure can range from 10 ml to 200 ml. The commenter also believed that CMS should pay for LOCM drugs separately in the hospital outpatient setting because they are paid as such in the physician office setting. Therefore, the commenter recommended that CMS exercise its discretion to apply an exception to the packaging rule to LOCM as it did with the anti-emetics and allow separate payment for LOCM drugs in CY 2005. The commenter also suggested that CMS assign the unit descriptor ''per 10 ml'' to HCPCS codes A4644, A4645, and A4646.

Response: We recognize that the commenter is concerned about the packaging of the three LOCM products. Based on the methodology used to calculate median cost per day for drugs and biologicals, as explained in section V.B.2. of the preamble, we determined that the per day costs of these products were below $50. Therefore, these items were packaged. We note that the LOCM products are a unique class of drugs that have always been packaged from the beginning of the OPPS in August 1, 2000, and this is the first year that we looked into the cost data for these drugs to determine whether they should be paid separately. We realize that for CY 2005 these drugs will be packaged under the OPPS, but will receive separate payment in the physician office setting. However, based upon the statutory packaging threshold for drugs and biologicals as per administration cost less than $50, we believe that it is appropriate for us to package the LOCM drugs under the OPPS. With respect to adding unit descriptors to HCPCS code A4644, A4645, and A4646, we suggest that the commenter pursue these changes through the process set up by the National HCPCS Panel.

Comment: We received comments concerning the new Part D prescription drug benefit mandated by the MMA and the intersection between drugs covered by Part D and Part B.

Response: Because such issues are not within the scope of this CY 2005 OPPS

final rule with comment period, we will not respond to those comments in this document.

Comment: We received many comments from makers of drug and biological products, national trade associations, and an association for cancer centers suggesting that CMS should expand the future rate-setting methodology for ''specified covered outpatient drugs'' to include all drugs and biologicals that either are or were previously paid separately under the OPPS, regardless of whether the drugs meet or exceed the $50 threshold. The commenters also recommended that CMS also work with GAO and MedPAC to ensure that their respective studies of the acquisition costs and pharmacy service and overhead costs include all of these drugs and biologicals and that the studies are thorough and will contain all the information CMS needs to set proper payment rates in the future. Many of these commenters were concerned about CMS' use of claims, other data, and the methodologies used to establish the OPPS payments for drugs and biologicals that do not meet the definition of ''specified covered outpatient drugs'' and therefore, are not statutorily required to be included in these studies. The commenters suggested that CMS should not implement different methodologies for ''specified covered outpatient drugs'' and other separately paid drugs in CY 2006; instead, CMS should ensure appropriate payment for all Medicare covered drugs by applying the acquisition cost-based payment methodology to all separately paid drugs. One commenter believed that Congress fully intended for all separately paid drugs and biologicals to be paid based on hospital acquisition costs, as informed by these studies. Another commenter recommended that CMS continue to accept external cost data that may be submitted by knowledgeable stakeholders, such as manufacturers, providers, or patients to provide verification of hospital acquisition costs for specific drugs and biologicals. One commenter indicated that it would like to work with CMS as it prepares the hospital acquisition cost survey for the CY 2006 rates.

Response: We appreciate the interest expressed by many of the commenters regarding the MMA-mandated surveys that will be conducted by the GAO and MedPAC of hospital acquisition cost for drugs and biologicals and their overhead and related costs, respectively. However, we note that these provisions of the MMA affect payment for drugs and biologicals in CY 2006, and thus, these comments fall outside the scope of this rule. Therefore, we will not be responding to these comments at this time.

Comment: A commenter requested that CMS examine every HCPCS J-code for drugs to ensure that the dosage definitions for the HCPCS codes are set at the lowest available manufacturers' dosage and match the customary dispensing packaging.

Response: Changes to the HCPCS J-codes are made by the National HCPCS Panel; therefore, this comment is outside the scope of this OPPS final rule. We suggest that the commenter pursue these changes through the process established by the National HCPCS Panel.

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Table 32. – CY 2005 APC Payment Rates for Drugs, Biologicals, and Radiopharmaceuticals (Based on Median Cost)

HCPCS	Status Indicator	APC	Short Description	CY 2005 Payment Rate
A4643	K	9026	High dose contrast MRI	$26.24
A4647	K	9027	Supp- paramagnetic contr mat	$35.59
J0120	K	9028	Tetracyclin injection	$99.99
J0150	K	0379	Injection adenosine 6 MG	$12.33
J0152	K	0917	Adenosine injection	$8.71
J0282	K	9029	Amiodarone HCl	$11.00
J0285	K	9030	Amphotericin B	$20.64
J0395	K	9031	Arbutamine HCl injection	$68.08
J0475	K	9032	Baclofen 10 MG injection	$10.68
J0740	K	9033	Cidofovir injection	$407.58
J0743	K	0846	Cilastatin sodium injection	$11.37
J0900	K	0848	Testosterone enanthate inj	$38.27
J0945	K	9034	Brompheniramine maleate inj	$59.01
J1051	K	9035	Medroxyprogesterone inj	$17.56
J1212	K	9036	Dimethyl sulfoxide 50% 50 ML	$53.34
J1230	K	9037	Methadone injection	$13.32
J1245	K	0380	Dipyridamole injection	$11.70
J1410	K	9038	Inj estrogen conjugate 25 MG	$45.51
J1452	K	9040	Intraocular Fomivirsen na	$939.79
J1455	K	0866	Foscarnet sodium injection	$11.80
J1460	K	9041	Gamma globulin 1 CC inj	$31.63
J1610	K	9042	Glucagon hydrochloride/1 MG	$46.16
J1742	K	9044	Ibutilide fumarate injection	$123.79
J1750	K	9045	Iron dextran	$14.78
J1756	K	9046	Iron sucrose injection	$0.53
J1835	K	9047	Itraconazole injection	$42.10
J2260	K	7007	Inj milrinone lactate / 5 MG	$8.22
J2597	K	9048	Inj desmopressin acetate	$4.52
J2725	K	9049	Inj protirelin per 250 mcg	$40.81
J2760	K	0845	Phentolaine mesylate inj	$20.82
J2916	K	9050	Na ferric gluconate complex	$6.03
J2995	K	0911	Inj streptokinase /250000 IU	$43.41
J2997	K	7048	Alteplase recombinant	$18.04
J3350	K	9051	Urea injection	$69.74
J3365	K	7036	Urokinase 250,000 IU inj	$124.64
J3530	K	9053	Nasal vaccine inhalation	$92.41
J7342	K	9054	Metabolically active tissue	$7.15
J7350	K	9055	Injectable human tissue	$8.05
P9041	K	0961	Albumin (human),5%, 50ml	$18.82
P9045	K	0963	Albumin (human), 5%, 250 ml	$60.54
P9046	K	0964	Albumin (human), 25%, 20 ml	$13.01
P9047	K	0965	Albumin (human), 25%, 50ml	$52.32

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e. CY 2005 Change in Payment Status for HCPCS Code J7308

Since implementation of the OPPS on August 1, 2000, HCPCS code J7308 (Aminolevulinic acid HCI for topical administration, 20 percent single unit dosage form) has been treated as a packaged item and denoted as such using status indicator ''N''. Thus, historically we have not allowed separate payment for this drug under the OPPS and it does not meet the statutory definition of a specified covered outpatient drug. For CY 2005, we proposed to allow separate payment for this drug at 106 percent of ASP, which is equivalent to the payment rate that it would receive under the Medicare Physician Fee Schedule. We proposed a CY 2005 ASP and payment under the OPPS for HCPCS code J7308 of $88.86. We solicited comments on our proposed payment methodology for HCPCS code J7308 for CY 2005.

We did not receive any comments on our proposed policy. However, we did receive a comment on this policy in response to the January 6, 2004 interim final rule with comment period, which we discuss below.

Comment: One commenter requested that HCPCS code J7308 be paid separately under the OPPS because its cost is in excess of the $50 median cost per day threshold, and the drug is also paid separately under the Medicare Physician Fee Schedule in CY 2004.

Response: We agree with the commenter and will finalize our policy to pay separately for J7308 at the payment rate that it would receive under the Medicare Physician Fee Schedule. The payment rate listed in Addenda A and B of the August 16, 2005 proposed rule was based on the second quarter ASP submission for CY 2004. As stated in section V.A. 3. of this final rule with comment period, we plan to make any appropriate adjustments to the amount shown in Addenda A and B if later quarter ASP submissions indicate that adjustments to the payment rate for this drug is necessary.

4. Public Comments Received on the January 6, 2004 Interim Final Rule With Comment Period and Departmental Responses

As discussed in section V.B.3. of this final rule with comment period, on January 6, 2004, we published in the **Federal Register** an interim final rule with comment period (69 FR 822) that implemented section 621(a)(1) of Pub. L. 108–173. Section 621(a)(1) specified payment limits on three categories of specific covered outpatient drugs and defined these three categories of drugs.

We received many pieces of correspondence that contained public comments associated with the January 6, 2004 interim final rule with comment period. Many of the comments expressed concerns about the following issues: treating radiopharmaceuticals as ''drugs;'' establishing mechanisms to pay for drugs without HCPCS codes at 95 percent of AWP; correcting the classification of specific items to sole source ''specified covered outpatient drugs;'' eliminating the use of ''equitable adjustments'' to the OPPS payment for drugs and biologicals or applying any functional equivalence standards; paying separately for drugs that are either packaged or whose payment is based on median cost as ''specified covered outpatient drugs''; expanding the list of items that will be studied in the MMA-mandated GAO and MedPAC surveys of certain OPD services; using the cost-to-charge methodology and the hospital outpatient claims data to set payment rates for certain drugs and biologicals; identifying and establishing appropriate payment rates for innovator and noninnovator multiple source drugs; and changing HCPCS code descriptors for radiopharmaceuticals to reflect the products as administered to patients.

We will not address these comments separately in this section because these issues are discussed in detail throughout this entire section (section V.) of this final rule with comment period. However, for those public comments that are not specifically addressed in section V., a summary of them and our responses to those comments follow:

Comment: A commenter suggested that CMS create separate HCPCS codes for Neoral, Sandimmune, and the other cyclosporine products. The commenter indicated that currently all of these products are being billed using HCPCS code J7502 (Cyclosporine, oral, 100 mg). The commenter stated that the payment rates for the brand name products should not be linked to the payment rates for the non-innovator products because this situation creates access issues to the branded products, and CMS should not limit patient access to the specific formulation deemed medically appropriate for the individual needs of the specific patients.

Response: We note that for both CYs 2004 and 2005, hospitals can use HCPCS code C9438 to bill for the brand name forms of oral cyclosporine. As stated V.A.3.a. of this final rule with comment period, the MMA set forth different payment ceilings for the brand and generic versions of a drug where the CY 2005 payment rate for innovator multiple source (brand name) drugs may not exceed 68 percent of the reference AWP and the payment for generic versions may not exceed 46 percent of the reference AWP. We explained previously that we apply those ceilings only where the payment for an item based on the median hospital cost for the drug exceeds one of these ceilings. In some cases, the payment based on the median hospital cost falls below the 46 percent ceiling for generic drugs. In such cases, the payment rate would be the same for brand and generic versions. We believe that basing payment for these items on relative hospital costs, with the application as appropriate of the previously mentioned ceilings not only meets the intent but also the requirements of the MMA.

Comment: A commenter recommended that CMS consider pricing information from several authoritative sources when determining the reference AWP, including Red Book and First Data Bank, on a case-by-case basis since such pricing information can be used to resolve outstanding payment issues and ensure greater accuracy in calculating the OPPS payment rates.

Response: We appreciate this comment and will consider this recommendation when we reassess the OPPS payment rates.

Comment: Several commenters noted that CMS changed the classification for many of the biologicals products to sole source ''specified covered outpatient drugs'' in the February 27, 2004 CMS Transmittal 113 without discussing why the changes were made. One of the commenters indicated that the definition for sole source ''specified covered outpatient drugs'' in the MMA is different from the Medicaid rebate definition. The commenter stated that the MMA defined sole source drugs as: (1) A biological product (as defined under section 1861(t)(1) of the Act); or (2) a single source drug (as defined in section 1927(k)(7)(A)(iv) of the Act). The commenters requested that CMS clarify that it intends to treat all biological products as sole source drugs in the future as the law requires.

Response: We agree with the commenters that biologicals products are defined as sole source ''specified covered drugs'' in the MMA, and we will determine payment rates for these products accordingly.

Comment: We received several comments on the mechanism for establishing payment rates for innovator and noninnovator multiple source drugs. One commenter urged CMS to set the payment rates closer to the actual

costs for all products and services and provide differential reimbursement for innovator multiple source products only if their actual acquisition costs were markedly higher than that for the noninnovator multiple source products. Another commenter indicated that innovator and noninnovator multiple source drugs were discounted very similarly, and therefore, differential payments were not necessary. A commenter also requested that CMS obtain legislative approval to price these innovator and noninnovator multiple source drugs using a blended payment rate set halfway between 46 percent and 68 percent of their reference AWPs.

Response: We appreciate these suggestions and note that the methodology that will be used to determine payment rates for innovator and noninnovator multiple source drugs in CY 2005 is described in detail in section V.A.3.a. of this final rule with comment period.

C. Coding and Billing for Specified Outpatient Drugs

As discussed in the January 6, 2004 interim final rule with comment period (69 FR 826), hospitals were instructed to bill for sole source drugs using the existing HCPCS code, which were priced in accordance with the provisions of newly added section 1833(t)(14)(A)(i) of the Act, as added by Pub. L. 108–173. However, at that time, the existing HCPCS codes did not allow us to differentiate payment amounts for innovator multiple source and noninnovator multiple source forms of the drug. Therefore, effective April 1, 2004, we implemented new HCPCS codes via Program Transmittal 112 (Change Request 3144, February 27, 2004) and Program Transmittal 132 (Change Request 3154, March 30, 2004) that providers were instructed to use to bill for innovator multiple source drugs in order to receive appropriate payment in accordance with section 1833(t)(14)(A)(i)(II) of the Act. Providers were also instructed to continue to use the current HCPCS codes to bill for noninnovator multiple source drugs to receive payment in accordance with section 1833(t)(14)(A)(i)(III). In this manner, drugs, biologicals, and radiopharmaceuticals will be appropriately coded to reflect their classification and be paid accordingly. In the August 16, 2004 proposed rule, we proposed to continue this coding practice in CY 2005 with payment made in accordance with section 1833(t)(14)(A)(ii) of the Act.

We received a few public comments on our proposal.

Comment: Several commenters urged that CMS delete certain newly created C codes (C9400,Thallous Chloride, brand; C9401 Strontium–89 chloride, brand; C9402 Th I131 so iodide cap, brand; C9403 Dx I131 so iodide cap, brand; C9404 Dx So iodide sol, brand; C9405 Th I131 so iodide, sol. brand) because radiopharmaceuticals are better characterized as either sole source or innovator multiple source drugs. The commenters indicated that the creation of the new codes implied that some radiopharmaceuticals are generic products and others are brand, but there was no identification of which product falls within which code. Further, there was no payment difference between some of the radiopharmaceutical brand products versus generics. The commenters believed these products did not fit the conventional brand versus generic distinctions, and should all be recognized as brand drugs until the GAO report provides additional data. Also, the commenters recommended that the current A-codes be retained at the payment levels CMS proposes for ''brand'' drugs and believed that deletion of these codes should result in payment for the corresponding radiopharmaceuticals based on their status as a sole source or innovator multi-source drug and would significantly lessen hospital administrative burden and confusion. Another commenter indicated that hospitals needed further clarification on which manufacturers' products can be billed under the HCPCS codes created for the brand and generic forms of a product.

Response: As stated in section V.A.3.a. of this final rule with comment period, section 621(a) of Pub. L. 108–173 sets forth different payment ceilings for the brand and generic versions of a drug where the CY 2005 payment rate for innovator multiple source (brand name) drugs may not exceed 68 percent of the reference AWP and the payment for generic versions may not exceed 46 percent of the reference AWP. We explained previously that we apply those ceilings only where the payment for an item based on the median hospital cost for the drug exceeds one of these ceilings. In some cases, the payment based on the median hospital cost falls below the 46 percent ceiling for generic drugs. In such cases, as the commenters indicate, the payment rate would be the same for brand and generic versions.

We will not be providing a list of brand name and generic products for hospitals to use in determining whether their product is a brand name or generic product. We believe that hospitals are in the best position to correctly determine which type of products they are using. We refer the commenter to the definitions of innovator and noninnovator multiple source drugs stated in the January 6, 2004 interim final rule with comment period (69 FR 822). Hospitals can also use the FDA's Orange Book in determining whether an item they use is a brand name product.

D. Payment for New Drugs, Biologicals and Radiopharmaceuticals Before HCPCS Codes Are Assigned

1. Background

Historically, hospitals have used a code for an unlisted or unclassified drug, biological, or radiopharmaceutical or used an appropriate revenue code to bill for drugs, biologicals, and radiopharmaceuticals furnished in the outpatient department that do not have an assigned HCPCS code. The codes for not otherwise classified drugs, biologicals, and radiopharmaceuticals are assigned packaged status under the OPPS. That is, separate payment is not made for the code, but charges for the code would be eligible for an outlier payment and, in future updates, the charges for the code are packaged with the separately payable service with which the code is reported for the same date of service.

Drugs and biologicals that are newly approved by the FDA and for which an HCPCS code has not yet been assigned by the National HCPCS Alpha-Numeric Workgroup could qualify for pass-through payment under the OPPS. An application must be submitted to CMS in order for a drug or biological to be assigned pass-through status, along with a temporary C-code for billing purposes, and an APC payment amount. Pass-through applications are reviewed on a flow basis, and payment for drugs and biologicals approved for pass-through status is implemented throughout the year as part of the quarterly updates of the OPPS.

In the November 7, 2003 final rule with comment period (68 FR 63440), we explained how CMS generally pays under the OPPS for new drugs and biologicals that are assigned HCPCS codes, but that are not approved for pass-through payment, and for which CMS had no data upon which to base a payment rate. These codes do not receive separate payment, but are assigned packaged status. Hospitals were urged to report charges for the new codes even though separate payment is not provided. Charges reported for the new codes are used to determine hospital costs and payment rates in future updates. For CY 2004, we again

noted that drugs that were assigned an HCPCS code effective January 1, 2004, and that were assigned packaged status, remain packaged unless pass-through status is approved for the drug. If pass-through status is approved for these drugs, pass-through payments are implemented prospectively in the next available quarterly release.

2. Provisions of Pub. L. 108–173

Section 621(a)(1) of Pub. L. 108–173 amended section 1833(t) of the Act by adding paragraph (15) to provide for payment for new drugs and biologicals until HCPCS codes are assigned under the OPPS. Under this provision, we are required to make payment for an outpatient drug or biological that is furnished as part of covered OPD services for which a HCPCS code has not been assigned in an amount equal to 95 percent of AWP. This provision applies only to payments under the OPPS, effective January 1, 2004. However, we did not implement this provision in the January 6, 2004 interim final rule with comment period because we had not determined at that time how hospitals would be able to bill Medicare and receive payment for a drug or biological that did not have an identifying HCPCS code.

As stated earlier, at its February 2004 meeting, the APC Panel heard presentations suggesting how to make payment for a drug or biological that did not have a code. The APC Panel recommended that we work swiftly to implement a methodology to enable hospitals to file claims and receive payment for drugs that are newly approved by the FDA. The APC Panel further recommended that we consider using temporary or placeholder codes that could be quickly assigned following FDA approval of a drug or biological to facilitate timely payment for new drugs and biologicals.

We explored a number of options to make operational the provisions of section 1833(t)(15) of the Act, as added by section 621(a)(1) of Pub. L. 108–173, as soon as possible. One of the approaches that we considered was to establish a set of placeholder codes in the Outpatient Code Editor (OCE) and the PPS pricing software for the hospital OPPS (PRICER) that we would instruct hospitals to use when a new drug was approved. Hospitals would be able to submit claims using the new code but would receive no payment until the next quarterly update. By that time, we would have installed an actual payment amount and descriptor for the code into the PRICER, and would mass-adjust claims submitted between the date of FDA approval and the date of installation of the quarterly release. A second option that we considered was to implement an APC, a C-code, and a payment amount as part of the first quarterly update following notice of FDA approval of a drug or biological. Hospitals would hold claims for the new drug or biological until the quarterly release was implemented and then submit all claims for the drug or biological for payment using the new C-code to receive payment on a retroactive basis. We also considered instructing hospitals to bill for a new drug or biological using a ''not otherwise classified'' code for which they would receive an interim payment based on charges converted to cost. Final payment would then be reconciled at cost report settlement. While each of these approaches might enable hospitals to begin billing for a newly approved drug or biological as soon as it received FDA approval, each approach had significant operational disadvantages, such as increased burden on hospitals or payment delays, or the risk of significant overpayments or underpayments that could not be resolved until cost report settlement.

We adopted an interim approach that we believe balances the need for hospitals to receive timely and accurate payment as soon as a drug or biological is approved by the FDA with minimal disruption of the OPPS claims processing modules that support the payment of claims. On May 28, 2004 (Transmittal 188, Change Request 3287), we instructed hospitals to bill for a drug or biological that is newly approved by the FDA by reporting the National Drug Code (NDC) for the product along with a new HCPCS code C9399, Unclassified drug or biological. When C9399 appears on a claim, the OCE suspends the claim for manual pricing by the fiscal intermediary. The fiscal intermediary prices the claim at 95 percent of its AWP using Red Book or an equivalent recognized compendium, and processes the claim for payment. This approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product-specific HCPCS to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. Hospitals would discontinue billing C9399 and the NDC upon implementation of an HCPCS code, status indicator, and appropriate payment amount with the next quarterly update.

In the August 16, 2004 proposed rule, we proposed to formalize this methodology for CY 2005 and to expand it to include payment for new radiopharmaceuticals to which a HCPCS code is not assigned (see section V.G. of this preamble). We solicited comments on the methodology and expressed particular interest in the reaction of hospitals to using this approach to bill and receive timely payment under the OPPS for drugs, biologicals, and radiopharmaceuticals that are newly approved by the FDA, prior to assignment of a product-specific HCPCS code.

We received a number of public comments on our proposal.

Comment: One commenter, a state hospital association, is concerned about the ability of hospitals to correctly code for newly approved drugs and biologicals without HCPCS codes using the NDC codes. The commenter indicates that typically only pharmacy systems within hospitals can properly handle the assignment and reporting of a drug's NDC, not the hospital billing systems. Additionally, the use of the Remarks field to report the NDC creates payment delays as it requires manual review and pricing by the fiscal intermediaries. Several commenters, including a national hospital association and several state hospital associations, recommended that CMS adopt a new revenue code subcategory for hospitals to use when reporting these newly FDA-approved drugs and biologicals on UB–92 paper claims. The hospital could use the new revenue code along with the reported NDC in the revenue-code description field. Establishing a new revenue code field, to be used with the description field, allows clearinghouses to scan the paper UB–92 and then convert the data into the appropriate HIPAA standard for auto adjudication. The FI would then no longer have to suspend these paper claims for manual pricing, because it would build logic into the system to auto-adjudicate these claims. The hospital would then continue to report C9399 (HCPCS code indicating Unclassified drug or biological) in the HCPCS field, the units in the Unit field, the date the drug was administered in the date field, and finally, the price of these drugs in the Total Charges field. These commenters believed that this alternative policy would greatly improve the current process for both hospitals and fiscal intermediaries.

Response: We read the hospital associations' recommendation for an alternative approach to report NDCs on UB–92 paper claims with interest and will explore its feasibility with the different components within CMS that are responsible for claims processing, information technology and systems,

and HIPAA standards. It appears that time-consuming systems changes could be required were we to adopt such an approach, which could delay implementation, but we will consider the proposal carefully.

Comment: A maker of pharmaceuticals commends CMS for implementing the mechanism where hospitals can bill and be paid for new drugs without HCPCS codes. However, the commenter is concerned that the use of a miscellaneous code may result in significant payment delays and potentially prevent patient access to new therapies. The commenter suggests that CMS monitor claims submission, timely processing, and payments more closely so that patient access to new therapies is not impeded. Another commenter suggested that CMS should modify this mechanism if necessary to ensure patients have access to cutting-edge drugs. One commenter suggested that CMS explore with its contractors the feasibility of automating processing of these claims by including the NDC number as a claims processing field when the miscellaneous C code appears on a claim since such a process would eliminate the additional costs of manual claim review and expedite provider payment.

Response: We share the commenters' concerns that claims processing systems not impede beneficiary access to new drug therapies. However, we believe the approach that we implemented in CY 2004 and that we proposed to adopt permanently beginning in CY 2005, which requires the use of HCPCS code C9399 to be reported with an appropriate NDC, will result in hospitals receiving payment for new drugs more quickly compared to the process that we followed previously, even though some manual handling of claims is required. We agree with the commenter who suggested that CMS closely monitor claims submission, timely processing, and payments for new drugs, and we intend to do so.

Comment: One commenter encouraged CMS to reconsider the payment policy that requires the reporting of the NDC for new drugs as ''mandatory'' and consider making the NDC ''optional.'' For providers unable to automate the reporting of the NDC number due to software limitations, it suggested that CMS consider allowing providers the option of listing the NDC number in the detailed drug name as reported on the itemized statement of charges that can be requested along with the UB reporting the C9399 code.

Response: As we have indicated in previous responses to commenters' suggestions regarding ways to implement the payment requirement for new drugs and biologicals that have not been assigned a HCPCS code, we will also consider this commenter's recommendation to determine its feasibility.

Comment: Several commenters urged CMS to reconsider the policy of preloading several new codes into CMS' computer system and assigning them to new drugs and biologicals as the Food and Drug Administration approved them, rather than requiring manual processing of claims using a single miscellaneous code. If CMS determines that the current policy is imposing too great an administrative burden on hospitals and delays in processing claims that harm hospitals' ability to provide new drugs and biologicals to Medicare beneficiaries, the commenters urged CMS to reconsider its proposal and to explore preloading placeholder codes instead.

Response: Preloading placeholder codes was one of the options that we considered before we implemented C9399, but we found that this approach had its disadvantages, most of which stemmed from concerns about delays related to the dissemination of new codes to providers and installing prices into the claims processing modules in a timely manner. We propose to monitor throughout CY 2005 the use of HCPCS code C9399 and NDC codes to evaluate whether this approach is an improvement over how hospitals were previously paid for new drugs to which a HCPCS code had not been assigned and to determine if changes in the process would be beneficial.

Comment: One commenter indicated that requiring hospitals to submit the National Drug Code on claims imposes an enormous administrative burden on hospitals because there is no field for NDCs on the claims form and, therefore, NDCs cannot be entered on the claim automatically. Rather, claims must be flagged and adjusted manually. The commenter suggested that the best solution is to close the lag time between FDA approval and HCPCS assignment of a new drug. By creating a seamless execution of approval and code assignment, CMS can ensure that the MMA mandate is fulfilled in the least burdensome manner and that providers are adequately paid for providing these new drugs.

Response: While the use of NDCs may impose a degree of reporting burden on hospitals, we believe that, in spite of the inconvenience of manual reporting and claims processing, this approach is the most efficient way to expedite payment to hospitals for newly approved drugs to which a HCPCS code has not been assigned.

Comment: One commenter, an association for cancer centers, supported CMS' proposal for reporting new drugs without HCPCS codes using C9399 and any other necessary data. However, the commenter requested clarification from CMS on whether C9399 can only be used for injectible drugs or whether this code can also be used to report all newly approved FDA drugs (including oral drugs). The commenter believed that C9399 can be used for all Medicare-covered drugs, including oral anti-emetics and oral chemotherapeutics with IV equivalents, but requested that CMS clarify this issue to ensure that fiscal intermediaries correctly process this new code.

Response: Our instructions regarding how hospitals may report a new drug using C9399 and NDCs only indicate the method by which hospitals can bill Medicare for payment if the new drug is covered by the Medicare program. These instructions do not represent a determination that the Medicare program covers a new drug for which a hospital submits a bill using C9399. In addition to determining payment, fiscal intermediaries must determine whether a drug billed with C9399 meets all program requirements for coverage. For example, they must assess whether the drug is reasonable and necessary to treat the beneficiary's condition and whether the drug is excluded from payment because it is usually self-administered. The same rules, regulations, and policies that apply to coverage of drugs, biologicals, and radiopharmaceutical agents that already have a HCPCS code also apply to newly approved items for which a HCPCS code has not yet been assigned.

Comment: Two commenters urged CMS to publish the approved drugs and radiopharmaceuticals that may be submitted under HCPCS code C9399, as well as the appropriate units of measure applicable for each drug or biological and the payment amount for the drug based on 95 percent of the AWP. One commenter indicated that hospitals are concerned that they will not identify all of the drugs that are eligible for this payment and are also concerned that they may inappropriately assign the HCPCS code to drugs that are not eligible for this payment. Additionally, there is an administrative burden placed both on providers and the fiscal intermediaries when CMS does not publish the payment rates for these drugs.

Response: We understand that use of C9399 and NDCs is a departure from how hospitals have become accustomed

to preparing Medicare claims for the OPPS services. However, the MMA mandates that hospitals be paid 95 percent of AWP for new drugs until a HCPCS code is assigned to that drug. We believe this MMA provision is intended to ensure that hospitals can receive timely payment for new drugs, biologicals, and radiopharmaceuticals without having to wait for a HCPCS code to be created and disseminated or for an OPPS payment amount to be implemented in a quarterly OPPS update. Generally, CMS learns of FDA approval of a new product at approximately the same time the public learns of the approval. Hospitals may wish to look to their advocacy associations for assistance in monitoring the FDA Web site to identify new products as they are approved, as a supplemental information source. We also intend to explore ways hospitals could systematically receive timely reports of newly approved drugs by means other than checking the FDA Web site. However, how to report a product rests with the hospital, as it does for any drug, biological, radiopharmaceutical agent, procedure, or service, with or without a HCPCS code. Therefore, we are not accepting the commenters' suggestion that we publish the approved drugs and radiopharmaceuticals that may be submitted under HCPCS code C9399, as well as the appropriate units of measure applicable for each drug or biological and the payment amount for the drug based on 95 percent of the AWP. Rather, we prefer to focus our resources on updating the OPPS on a quarterly basis with codes, APC assignments, and payment amounts for drugs, biologicals, and radiopharmaceuticals newly approved by the FDA during the prior quarter.

We have carefully considered commenters' recommendations and concerns, and we believe that our proposed methodology for using C9399 and NDC codes to bill for drugs, biologicals, and radiopharmaceutical agents newly approved by FDA to which a HCPCS code is not assigned is the most efficient and practicable approach at this time to ensure timely, appropriate Medicare payment for these new products. Therefore, we are making final for CY 2005 our proposed methodology, without modification.

E. Payment for Vaccines

Outpatient hospital departments administer large numbers of immunizations for influenza (flu) and pneumococcal pneumonia (PPV), typically by participating in immunization programs. In recent years, the availability and cost of some vaccines (particularly the flu vaccine) have fluctuated considerably. As discussed in the November 1, 2002 final rule (67 FR 66718), we were advised by providers that the OPPS payment was insufficient to cover the costs of the flu vaccine and that access of Medicare beneficiaries to flu vaccines might be limited. They cited the timing of updates to the OPPS rates as a major concern. They indicated that our update methodology, which uses 2-year-old claims data to recalibrate payment rates, would never be able to take into account yearly fluctuations in the cost of the flu vaccine. We agreed with this concern and decided to pay hospitals for influenza and pneumococcal pneumonia vaccines based on a reasonable cost methodology. As a result of this change, hospitals, home health agencies (HHAs), and hospices, which were paid for these vaccines under the OPPS in CY 2002, have been receiving payment at reasonable cost for these vaccines since CY 2003. We are aware that access concerns continue to exist for these vaccines. However, we continue to believe that payment other than on a reasonable cost basis would exacerbate existing access problems. Therefore, in the August 16, 2004 proposed rule, we proposed to continue paying for influenza and pneumococcal pneumonia vaccines under the reasonable cost methodology in CY 2005.

Comment: Several commenters applauded CMS' proposal to continue to pay for vaccines under the reasonable cost methodology. The commenters indicated that payment on a reasonable cost basis helps ensure that the OPPS rates are adequate to cover hospitals' costs of providing vaccines to Medicare beneficiaries, protecting their health, and reducing Medicare's costs of treating influenza and other preventable illnesses.

Response: We appreciate the commenters' continued support of our policy to pay for influenza and pneumococcal pneumonia vaccines at reasonable cost and finalize our proposal in this final rule with comment period. We note that for CY 2005 a new CPT code for an influenza vaccine was created. The new CPT code 90656 (Influenza virus vaccine, split virus, preservative free, for use in individuals 3 years and above, for intramuscular use) will be paid at reasonable cost in CY 2005. We have assigned status indicator ''L'' (Not Paid under OPPS. Paid at reasonable cost) to this new CPT code.

F. Changes in Payment for Single Indication Orphan Drugs

Section 1833(t)(1)(B)(i) of the Act gives the Secretary the authority to designate the hospital outpatient services to be covered. The Secretary has specified coverage for certain drugs as orphan drugs (section 1833(t)(14)(B)(ii)(III) of the Act as added by section 621(a)(1) of Pub. L. 108–173). Section 1833(t)(14)(C) of the Act as added by section 621(a)(1) of Pub. L. 108–173, gives the Secretary the authority in CYs 2004 and 2005 to specify the amount of payment for an orphan drug that has been designated as such by the Secretary.

We recognize that orphan drugs that are used solely for an orphan condition or conditions are generally expensive and, by definition, are rarely used. We believe that if the cost of these drugs were packaged into the payment for an associated procedure or visit, the payment for the procedure might be insufficient to compensate a hospital for the typically high cost of this special type of drug. Therefore, in the August 16, 2004 proposed rule, we proposed to continue making separate payments for orphan drugs based on their currently assigned APCs.

In the November 1, 2002 final rule (67 FR 66772), we identified 11 single indication orphan drugs that are used solely for orphan conditions by applying the following criteria:

- The drug is designated as an orphan drug by the FDA and approved by the FDA for treatment of only one or more orphan conditions(s).
- The current United States Pharmacopoeia Drug Information (USPDI) shows that the drug has neither an approved use nor an off-label use for other than the orphan condition(s).

Eleven single indication orphan drugs were identified as having met these criteria and payments for these drugs were made outside of the OPPS on a reasonable basis.

In the November 7, 2003 final rule with comment period (68 FR 63452), we discontinued payment for orphan drugs on a reasonable cost basis and made separate payments for each single indication orphan drug under its own APC. Payments for the orphan drugs were made at 88 percent of the AWP listed for these drugs in the April 1, 2003 single drug pricer, unless we were presented with verifiable information that showed that our payment rate did not reflect the price that is widely available to the hospital market. For CY 2004, Ceredase (alglucerase) and Cerezyme (imiglucerase) were paid at 94 percent of AWP because external data

submitted by commenters on the August 12, 2003 proposed rule caused us to believe that payment at 88 percent of AWP would be insufficient to ensure beneficiaries' access to these drugs.

In the December 31, 2003 correction of the November 7, 2003 final rule with comment period (68 FR 75442), we added HCPCS code J9017, arsenic trioxide (per unit) to our list of single indication orphan drugs. As of the time of our August 16, 2004 proposed rule, the following were the 12 orphan drugs that we have identified as meeting our criteria: J0205 Injection, alglucerase, per 10 units; J0256 Injection, alpha 1-proteinase inhibitor, 10 mg; J9300 Gemtuzumab ozogamicin, 5 mg; J1785 Injection, imiglucerase, per unit; J2355 Injection, oprelvekin, 5 mg; J3240 Injection, thyrotropin alpha, 0.9 mg; J7513 Daclizumab parenteral, 25 mg; J9015 Aldesleukin, per vial; J9017 Arsenic trioxide, per unit; J9160 Denileukin diftitox, 300 mcg; J9216 Interferon, gamma 1-b, 3 million units and Q2019 Injection, basiliximab, 20 mg. In the August 16, 2004 proposed rule, we did not propose any changes to this list of orphan drugs for CY 2005.

In the proposed rule, we noted that had we not classified these drugs as single indication orphan drugs for payment under the OPPS, they would have met the definition as a single source specified covered outpatient drug and been paid lower payments which could impede beneficiary access to these unique drugs dedicated to the treatment of rare diseases. Instead, for CY 2005, under our authority at section 1833(t)(14)(C) of the Act, we proposed to pay for all 12 single indication orphan drugs, including Ceredase and Cerezyme, at the rate of 88 percent of AWP or 106 percent of the ASP, whichever is higher. However, for drugs where 106 percent of the ASP would exceed 95 percent of AWP, payment would be capped at 95 percent of AWP, which is the upper limit allowed for sole source specific covered outpatient drugs. For example, Ceredase and Cerezyme would each be paid at 95 percent of the AWP because payment at ASP plus 6 percent for these two drugs not only exceeds 88 percent of the AWP but also exceeds 95 percent of the AWP. We proposed to pay the higher of 88 percent of AWP or 106 percent of ASP capped at 95 percent of AWP to ensure that beneficiaries will continue to have access to such important drugs.

We received the following comments to our August 16, 2004 proposed rule on single indication orphan drugs.

Comment: A few commenters recommended that CMS adopt the FDA's definition of an orphan drug as under the Orphan Drug Act. The commenters indicated that CMS should expand the current list of 12 single-indication orphan drugs that receive special treatment to include several other FDA-designated orphan drugs. One commenter requested that CMS adopt a utilization threshold to identify orphan drugs that would receive the special treatment rather than using its current criteria.

Response: Using the statutory authority in section 1833(t)(1)(B)(i) of the Act, which gives the Secretary broad authority to designate covered OPD services under the OPPS, we have established criteria which distinguish single-indication orphan drugs from other drugs designated as orphan drugs by the FDA under the Orphan Drug Act. Our determination to provide special payment for these drugs neither affects nor deviates from FDA's classification of any drugs as orphan drugs. The special treatment given to this subset of FDA-designated orphan drugs is intended to ensure that beneficiaries have continued access to these life-saving therapies given that these drugs have a relatively low volume of patient use, lack any other non-orphan indication and are typically very costly. Although we are not expanding our criteria to identify orphan drugs that will receive special payment for CY 2005, we will consider the commenters' recommendation of a utilization threshold in future changes to the OPPS orphan drug list.

Comment: We received comments from different drug manufacturers separately requesting that Campath (J9010, Alemtuzumab), Elitek (J2783, Rasburicase), Vidaza (C9218, Azacitidine for injectable suspension), and Botox (J0585, Botulinum toxin type A) be included in the list of single-indication orphan drugs that will receive special payment for CY 2005.

Response: After careful review of the requests for these four drugs to be included in the list of single-indication orphan drugs, we have determined that Campath (J9010) and Vidaza (C9218) do meet our criteria for inclusion in the list. Thus, effective for January 1, 2005, J9010 and C9218 will be paid in accordance with the payment policy for single indication orphan drugs for CY 2005. However, we have determined that Elitek (J2783) and Botox (J0585) do not meet the criteria for inclusion in the list because these drugs have an off-label use as indicated by the 2004 United States Pharmacopoeia Drug Information (USPDI).

Comment: Several commenters, including manufacturers of alpha-1 proteinase inhibitor (J0256) sold under the brand names Prolastin, Aralast and Zemaira, submitted comments expressing concern over the decrease in the payment rate for HCPCS J0256 from the CY 2004 level to the CY 2005 proposed rate. The majority of commenters requested that the payment rate for J0256 be frozen at the CY 2004 levels, rather than based on the AWP of Prolastin, the least expensive drug among the three name brands. As some commenters explained, Prolastin has experienced supply shortages in the past and if the payment rate for the alpha-1 therapy did not take into account the higher AWPs of Aralast or Zemaira, it would be inadequate to cover the actual acquisition costs of the drugs to hospitals.

The manufacturer of Aralast requested that CMS exclude pricing information associated with Prolastin when setting the payment rate for J0256. The commenter stated that although Prolastin is currently available and used in greater quantities than either Aralast or Zemaira , it has experienced supply shortages in the past. Therefore, according to the commenter, the payment rate for J0256 needs to be such that patients will have continued access to all three brand names. Alternatively, the commenter recommended that new HCPCS codes could be created so each brand name could be paid appropriately or CMS could freeze the payment rate for J0256 at the CY 2004 levels, as the majority of commenters recommended.

The manufacturer of Zemaira expressed concern that the proposed payment rate does not meet the actual hospital acquisition cost for this brand name, which is the newest of the three brand names to come on the market to be used in alpha-1 therapy.

We received a comment from an organization representing voluntary health organizations and individual patients that stated that the proposed payments for CY 2005 were adequate to avoid problems with access to the orphan drugs that patients with rare diseases need. In addition, the commenter requested that CMS take actions to monitor any changes in beneficiaries' access to orphan drugs as a result of payment changes, to review the claims database for changes in utilization patterns, to seek input from beneficiaries about access problems, and to inform beneficiaries about payment changes and the potential impact of such changes on their access.

We also received recommendations from a patient advocacy organization requesting that CMS work with the manufacturers of the alpha-1 therapy to obtain the data necessary to raise the proposed OPPS rate of $2.46 (per 10 mg) or to establish the ASP rate which may

enhance patient access to care. The commenter also recommended that CMS base the payment rate for J0256 on all available brands.

Response: After careful evaluation of the issues and concerns raised by commenters in response to our proposed rule, we recognize that our proposed payment rate for HCPCS code J0256 may create an unanticipated access problem during periods of short supply. Therefore, in order to ensure continued beneficiaries' access to this important drug, we will base the payment rate for HCPCS code J0256 on all three brands of the alpha-1 proteinase inhibitor currently available on the market. The adjusted AWP of HCPCS code J0256 will be based on the volume-weighted average of the three drugs. The adjusted AWP will be updated each quarter, as necessary, to reflect any changes in the individual AWP or relative weight of each drug in the calculation of the AWP for HCPCS code J0256. We would expect that as the volume and/or individual AWP increases or decreases for a brand, these changes will be captured in its relative weight and will be reflected in the adjusted AWP for HCPCS code J0256.

We share the commenters' concern for protecting beneficiaries' access to these therapies used for rare disease conditions. As part of our process of developing special payment rates for single indication orphan drugs in CY 2005, our analysis of CY 2003 claims data does not indicate a decrease in utilization of any orphan drugs that may signify barriers to beneficiaries' access to these drugs.

Comment: Several commenters recommended that CMS eliminate the 95 percent AWP cap on single-indication orphan drugs whose ASP plus 6 percent would exceed their 88 percent AWP. According to the commenters, these drugs would not be subject to the 95 percent AWP cap when administered in the physician's office. They argued that CMS should pay for these drugs at the same rate, irrespective of the site of service.

We received a request from the drug manufacturer of Ontak to increase the payment rate for the drug from 88 percent of the May 2004 AWP to 92 percent of the current AWP. Alternatively, the commenter requested that CMS remove the 95 percent AWP cap for J9160 (Ontak).

Response: We believe that access to these life-saving therapies is extremely important and after careful consideration, we will not implement the cap of 95 percent of AWP for any of the single-indication orphan drug for those drugs whose 106 percent ASP exceeds 88 percent of AWP. Effective for CY 2005, payment for all single-indication orphan drugs will be set at the higher of 106 percent of the most current ASP or 88 percent of the most current AWP.

Comment: A few commenters recommended that CMS update the payment rates quarterly, based on the latest ASP and AWP data available. They argue that to lock in the rates for a year based on outdated information could impede patient access to these drugs.

Response: We agree with the commenters and will base payments for single-indication orphan drugs on a quarterly comparison of ASP and AWP data. Appropriate adjustments to the payment amounts shown in Addendum A and B will be made if ASP submissions and AWP data in a later quarter indicate that adjustments to the payment rates are necessary. These changes to the Addenda will be announced in our program instructions released on a quarterly basis and posted on our Web site at *http://www.cms.hhs.gov.*

Comment: We also received a comment from the manufacturer of Fabrazyme requesting that CMS consider making payment for Fabrazyme (C9208, agalsidase beta) as a single-indication orphan drug. The commenter believes that by statute, CMS is required to pay for the drug at 106 percent of ASP; however, the commenter stated that if CMS were to somehow reach a different conclusion, it would request to be treated as a single-indication orphan drug.

Response: We agree with the commenter that the statute requires that payment for Fabrazyme (C9208), a drug that currently has pass-through status, be made at 106 percent of ASP for CY 2005.

In summary, we have set payment rates for single-indication orphan drugs according to the following policy, effective January 1, 2005:

- We are using the same criteria that we implemented in CY 2003 to identify single indication orphan drugs used solely for an orphan condition for special payment under the OPPS; and,
- We are setting payment under the CY 2005 OPPS for single indication orphan drugs at the higher of 88 percent of the AWP or the ASP plus 6 percent, updated quarterly to reflect the most current AWP and ASP data.

While we are not implementing the 95 percent AWP cap on single-indication orphan drugs in CY 2005, we will monitor this decision and may apply the cap in future OPPS updates.

G. Change in Payment Policy for Radiopharmaceuticals

In the November 1, 2002 OPPS final rule (67 FR 66757), we determined that we would classify any product containing a therapeutic radioisotope to be in the category of benefits described under section 1861(s)(4) of the Act. We also determined that the appropriate benefit category for diagnostic radiopharmaceuticals is section 1861(s)(3) of the Act. We stated in the November 1, 2002 final rule that we will consider neither diagnostic nor therapeutic radiopharmaceuticals to be drugs as defined in 1861(t) of the Act (67 FR 66757). Therefore, beginning with the CY 2003 OPPS update, and continuing with the CY 2004 OPPS update, we have not qualified diagnostic or therapeutic radiopharmaceuticals as drugs or biologicals.

As we stated in the August 16, 2004 proposed rule, when we analyzed the many changes mandated by Pub. L. 108–173 that affect how we would pay for drugs, biologicals, and radiopharmaceuticals under the OPPS in CY 2005, we revisited the decision that we implemented in CY 2003 not to classify diagnostic and therapeutic radiopharmaceuticals as drugs or biologicals. In our analysis, we noted that although we did not consider radiopharmaceuticals for pass-through payment in CYs 2003 and 2004, we did apply to radiopharmaceuticals the same packaging threshold policy that we applied to other drugs and biologicals, and which we proposed to continue in CY 2005. In addition, for the CY 2004 OPPS update, we applied the same adjustments to median costs for radiopharmaceuticals that we applied to separately payable drugs and biologicals that did not have pass-through status (68 FR 63441).

In our review of this policy, we noted that section 1833(t)(14)(B)(i) of the Act, as amended by section 621(a) of Pub. L. 108–173, does include ''radiopharmaceutical'' within the meaning of the term ''specified covered outpatient drugs,'' although neither section 621(a)(2) nor section 621(a)(3) of Pub. L. 108–173 includes a reference to radiopharmaceuticals.

In an effort to provide a consistent reading and application of the statute, we proposed to apply to radiopharmaceuticals certain provisions in section 621 of Pub. L. 108–173 which affect payment for drugs and biologicals billed by hospitals for payment under the OPPS. We believed it was reasonable to include radiopharmaceuticals in the general category of drugs in light of their

inclusion as specified covered outpatient drugs in section 1833(t)(14)(B) of the Act, as added by section 621(a)(1) of Pub. L. 108–173.

Section 621(a)(1) of Pub. L. 108–173, which amends section 1833(t) of the Act by adding a new subparagraph (14) affecting payment for radiopharmaceuticals under the OPPS, is unambiguous. This provision clearly requires that separately paid radiopharmaceuticals be classified as ''specified covered outpatient drugs.'' Therefore, in CY 2005, we proposed to continue to set payment for radiopharmaceuticals in accordance with these requirements, which are discussed in detail in section V.B.3. of this preamble.

Section 1833(t)(16)(B) of the Act, as added by section 621(a)(2) of Pub. L. 108–173, requires us to reduce the threshold for the establishment of separate APCs with respect to drugs and biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006. We proposed to apply the $50 packaging threshold methodology discussed in section V.B.2. of this final rule with comment period to radiopharmaceuticals as well as to drugs and biologicals.

Section 1833(t)(15) of the Act, added by section 621(a)(1) of Pub. L. 108–173, requires us to make payment equal to 95 percent of the AWP for an outpatient drug or biological that is covered and furnished as part of covered OPD services for which a HCPCS code has not been assigned. We proposed, beginning in CY 2005, to extend to radiopharmaceuticals the same payment methodology discussed in section V.D. of this preamble for new drugs and biologicals before HCPCS codes are assigned. That is, we proposed to pay for newly approved radiopharmaceuticals, as well as newly approved drugs and biologicals, at 95 percent of AWP prior to assignment of a HCPCS code.

Section 1833(t)(5)(E) of the Act, as added by section 621(a)(3) of Pub. L. 108–173, excludes separate drug and biological APCs from outlier payments. Beginning in CY 2005, we proposed to apply section 621(a)(3) of Pub. L. 108–173 to APCs for radiopharmaceuticals. That is, beginning in CY 2005, radiopharmaceuticals would be excluded from receiving outlier payments.

Consistent with our proposed policy to apply to radiopharmaceutical agents payment policies that apply to drugs and biologicals, we further proposed, beginning in CY 2005, to accept applications for pass-through status for certain radiopharmaceuticals. That is, we proposed on a prospective basis to consider for pass-through status those radiopharmaceuticals to which a HCPCS code is first assigned on or after January 1, 2005. As we explain in section V.A.3. of this final rule with comment period, section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs and biologicals as the amount determined under section 1842(o) of the Act. In the August 16, 2004 proposed rule, we proposed to pay for drugs and biologicals with pass-through status in CY 2005 consistent with the provisions of section 1842(o) of the Act as amended by Pub. L. 108–173, at a rate that is equivalent to the payment these drugs and biologicals would receive in the physician office setting and set in accordance with the methodology described in the Medicare Physician Fee Schedule Proposed Rule for CY 2005 (69 FR 47488, 47520 through 47524).

We issued an interim final rule with comment period entitled ''Medicare Program: Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals'' in the April 6, 2004 **Federal Register**, related to the calculation and submission of manufacturer's ASP data (69 FR 17935). We need these data in order to determine payment for drugs and biologicals furnished in a physician office setting in accordance with the methodology described in the Medicare Physician Fee Schedule Proposed Rule (69 FR 47488, 47520 through 47524). However, the April 6, 2004 interim final rule with comment period excludes radiopharmaceuticals from the data reporting requirements that apply to Medicare Part B covered drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act (69 FR 17935). As a consequence, we would not have the same type of data available to determine payment for a new radiopharmaceutical approved for pass-through status after January 1, 2005 that would be available to determine payment for a new drug or biological with pass-through status in CY 2005.

Therefore, in order to set payment for a new radiopharmaceutical approved for pass-through status in accordance with 1842(o) of the Act and in a manner that is consistent with how we proposed to set payment for a pass-through drug or biological, we proposed a methodology that would apply solely to new radiopharmaceuticals for which payment would be made under the OPPS and for which an application for pass-through status is submitted after January 1, 2005. That is, in order to receive pass-through payment for a new radiopharmaceutical under the OPPS, a manufacturer would be required to submit data and certification for the radiopharmaceutical in accordance with the requirements that apply to drugs and biologicals under section 303 of Pub. L. 108–173 as set forth in the interim final rule with comment period issued in the April 6, 2004 **Federal Register** (66 FR 17935) and described on the CMS Web site at *http://cms.hhs.gov.* We proposed that payment would be determined in accordance with the methodology applicable to drugs and biologicals that is discussed in the CY 2005 Medicare Physician Fee Schedule proposed rule (69 FR 47488, 47520–47524). In the event the manufacturer seeking pass-through status for a radiopharmaceutical does not submit data in accordance with the requirements specified for new drugs and biologicals, we proposed to set payment for the new radiopharmaceutical as a specified covered outpatient drug, under section 1833(t)(14)(A) as added by section 621(a)(1) of Pub. L. 108–173.

We received many public comments on our proposals.

Comment: Many commenters applauded CMS for proposing to treat radiopharmaceuticals as drugs and encouraged CMS to continue to pay for these products as ''specified covered outpatient drugs'' under the OPPS, consistent with section 621(a) of the MMA. They indicated that this policy ensures consistent treatment of drugs and radiopharmaceuticals, eliminates confusion related to the prior differences in their treatment under the OPPS, and facilitates patient access to these important therapies in clinically appropriate settings. One of the commenters also supported the proposal to exclude radiopharmaceuticals from receiving outlier payments in CY 2005.

Response: We appreciate the commenters' support of our policy to treat radiopharmaceuticals as drugs and will finalize this policy for CY 2005.

Comment: Several commenters opposed our proposal to require manufacturers to submit ASP data for radiopharmaceutical agents with pass-through status. One manufacturer of radiopharmaceuticals stated that there are significant practical problems and legal barriers to reporting ASP for radiopharmaceuticals. The commenter indicated that manufacturers often sell the components of a radiopharmaceutical to independent radiopharmacies. These radiopharmacies then sell unit doses to many hospitals; however, some hospitals also purchase the components

of the radiopharmaceutical and prepare the radiopharmaceutical through in-house radiopharmacies. This commenter asserted that the end result is that there is very often no ASP for the finished radiopharmaceutical product. For example, there may only be manufacturer pricing for the components; however, the price set by the manufacturer for one component of a radiopharmaceutical does not directly translate into the acquisition cost of the ''complete'' radiopharmaceutical, which may result from the combination of several components. This commenter recommended that CMS be consistent and not require ASP in the OPPS, as CMS does not require ASP for radiopharmaceuticals in the Medicare Physician Fee Schedule. The commenter thus urged CMS to determine payment for pass-through radiopharmaceuticals as specified covered outpatient drugs, based on AWP or acquisition costs. Another commenter recommended that CMS set payment for all pass-through radiopharmaceuticals in CY 2005 using the AWP-based ''specified covered outpatient drugs'' payment methodology, regardless of whether ASP data are available for the drug and stated that this methodology is more appropriate for these products, because it will be more likely to ensure adequate payment as use of the product is adopted, and thus will provide for robust cost data for future rate-setting purposes.

Response: We appreciate these comments and understand the concerns commenters stated regarding our proposal to require manufacturers of radiopharmaceutical agents with pass-through status to submit ASP data. We recognize the complexities of determining ASP for radiopharmaceuticals because of their unique preparation processes; therefore, we agree with the commenters' concerns about finalizing the proposed policy. Because radiopharmaceuticals are not paid on ASP in the physician office setting, manufacturers of these agents will not be required to report ASPs for payment purposes under the OPPS. Therefore, payment for radiopharmaceuticals with pass-through status will be made in accordance with their status as sole source ''specified covered outpatient drugs.'' That is, in the absence of both ASP data and hospital claims data, we will set payment for new radiopharmaceuticals approved for pass-through status beginning in CY 2005 at the floor for sole source ''specified coveraged outpatient drugs,'' which is 83 percent of the AWP.

Comment: A few commenters urged CMS to revise the HCPCS code descriptors for radiopharmaceutical products that do not currently have ''per dose'' or ''per study'' descriptors and indicated that ''per dose'' or ''per study'' code descriptors will facilitate the collection of more accurate charge and cost data which are necessary to establish equitable payment for radiopharmaceutical agents.

Response: We recognize the concerns expressed by these commenters. As we have stated in the November 7, 2003 OPPS final rule with comment period (68 FR 63451), we continue to believe that in changing descriptors to ''per dose'' or ''per study'', we will lose specificity with respect to the data we will receive from hospitals. We are not convinced that there is a programmatic need to change the radiopharmaceutical code descriptors to ''per dose'' or that claims data based on the current code descriptors are problematic for setting payment rates for these products. However, we will continue to work with industry representatives to ensure that the current HCPCS descriptors are appropriate and review this issue in the future, if needed. Furthermore, we stress the importance of proper coding by providers so that we can obtain accurate data for future rate setting.

Comment: A commenter strongly supported CMS requiring that hospitals report all HCPCS codes for drugs including those that are packaged and indicated that this will enable CMS to track costs and help to ensure that only correctly coded claims (those with radiopharmaceuticals) are used in setting payment rates for nuclear medicine procedures. Therefore, the commenter recommended that CMS require continued reporting of HCPCS codes for all radiopharmaceuticals (packaged and non-packaged products).

Response: We will continue to strongly encourage hospitals to report charges for all drugs using the correct HCPCS codes for the items used, including the drugs that have packaged status in CY 2005. We agree with the commenter that it is most useful to us when we have a robust set of claims for each item paid for under the OPPS. We would note, however, that with just a very few exceptions, hospitals do appear to be reporting charges for drugs, biologicals and radiopharmaceuticals using the existing HCPCS codes, even when such items have packaged status. At this time, we do not believe it is necessary to institute a requirement for drugs as we are doing for the device category codes. However, we will continue to monitor this through our annual analysis of claims data and will reconsider this in the future, if we determine that it is necessary.

H. Coding and Payment for Drug Administration

Since implementation of the OPPS, Medicare OPPS payment for administration of cancer chemotherapy drugs and infusion of other drugs has been made using the following HCPCS codes:

- Q0081, Infusion therapy other than chemotherapy, per visit
- Q0083, Administration of chemotherapy by any route other than infusion, per visit
- Q0084, Administration of chemotherapy by infusion only, per visit
- Q0085, Administration of chemotherapy by both infusion and another route, per visit

In the CY 2004 proposed rule, we proposed to change coding and payment for these services to enable us to pay more accurately for the wide range of services and the drugs that we package into these per visit codes. (Background discussion on these codes is included in the August 12, 2003 OPPS proposed rule (68 FR 47998). Commenters on the CY 2004 proposed rule recommended that we use the CPT codes for drug administration. One commenter provided a crosswalk from the CPT codes for drug administration to the Q codes that we could use in a transition. We did not implement this in the final rule for CY 2004 OPPS but indicated that we would consider it for CY 2005 and would discuss it with the APC Panel at its February 2004 meeting.

Commenters and the APC Panel recommended that we discontinue use of code Q0085 for CY 2004 because codes Q0083 and Q0084 could be used together to report the services described by code Q0085. We did implement this change for CY 2004 and made code Q0085 nonpayable for CY 2004 OPPS.

At the February 2004 APC Panel meeting, we presented a proposal from an outside organization that matched CPT codes for chemotherapy and nonchemotherapy infusions to the Q codes currently used to pay for these services under the OPPS. We asked the APC Panel for their perspective on the potential benefit of using the proposed coding approach as the basis for billing and determining the OPPS payment for administering these drugs. The APC Panel recommended that CMS continue to review the organization's proposed coding crosswalk with the goal of using it to transition from the use of Q-codes

to that of CPT codes to bill for administration of these drugs.

In the August 16, 2004 proposed rule, for CY 2005, we proposed to use the CPT codes for drug administration but to crosswalk the CPT codes into APCs that reflect how the services would have been paid under the Q codes. Although hospitals would bill the CPT codes and include the charges for each CPT code on the claim, payment would be made on a per visit basis, using the cost data from the per visit Q codes (Q0081, Q0083 and Q0084) to set the payment rate for CY 2005. See Table 29 of the proposed rule for the proposed crosswalk of CPT codes into APCs based on the Q codes (69 FR 50521). The only change from the crosswalk that was submitted by the outside organization is that we proposed a Q code and APC crosswalk for CPT code 96549 (Unlisted chemotherapy procedure), rather than bundling that service. We believe that Q0083 is the code that would have previously been reported by hospitals to describe the unlisted service. In addition, this would place the unlisted service in our lowest resource utilization APC for chemotherapy, consistent with our policy for other unlisted services.

We proposed to establish the Q code and APC crosswalk for CPT code 96549 because there is no CPT specific charge or frequency data on which to set payments. The CY 2005 OPPS is based on CY 2003 claims data which used the Q codes. Therefore, the only cost data available to us for establishment of median costs is the data based on the Q codes for drug administration. Moreover, the only frequency data that are available for use in calculating the scalar for budget neutrality of payment weights are the frequency data for the Q codes. Therefore, the payments set for the CPT codes must use the cost data for the Q codes and must result in the same payments that would have been made had the Q codes been continued.

Under this proposed methodology, hospitals would report the services they furnish with the CPT codes and would show the charges that they assign to the CPT codes on the claim. The Medicare OCE would assign the code to an APC whose payment is based on the per visit Q code that would have been used absent coding under CPT. In most cases, the OCE would collapse multiple codes or multiple units of the same CPT code into a single unit to be paid a single APC amount. This approach is needed because the data for the Q codes is reported on a per visit basis and more than one unit of a CPT code can be provided in a visit.

For example, CPT code 96410 (Chemotherapy administration infusion technique, up to 1 hour) is for infusion of chemotherapy drugs for the first hour, and CPT code 96412 is for chemotherapy infusion up to 8 hours, each additional hour. The claims data used to set the APC payment rate for these codes is for a per visit amount (taken from CY 2003 data for Q0084 a per visit code). The frequency data on the claim are also on a per visit basis. For CY 2005, we proposed that CPT code 96410 would be paid one unit of APC 0117 (to which CPT code 96410 would be crosswalked) and no separate payment would be made for CPT code 96412, regardless of whether one unit or more than one unit is billed. CPT code 96412 would be a packaged code for CY 2005. Under the Q code data on which the payment weight for APC 0117 is based, the per visit amount would represent a payment that is appropriate for all drug administration services in a visit (that is, one unit of CPT code 96410 and as many units of CPT code 96412 as were furnished in the same visit).

Similarly, we proposed that when a hospital bills 3 units of CPT code 96400 (Chemotherapy administration, subcutaneous or intramuscular, with or without local anesthesia), the OCE would assign one unit of APC 0116 for that code. (APC 0116 is the APC to which CPT code 96400 would be crosswalked.) The payment would be based on Q0083, a per visit code, because, absent the ability to be paid based on CPT codes, the hospital would have billed one unit of Q0083 (for the 3 injections) had we not discontinued the Q codes for CY 2005. The OCE would assume that there was one and only one visit in which there were 3 injections and would pay accordingly (that is, one unit of APC 0116).

We noted that if we adopt the CPT codes for drug administration to ensure accurate payment in the future, it would be critical for hospitals to bill the charges for the packaged CPT codes for drug administration for CY 2005 (that is, the CPT codes with SI=N), even though there would be no separate payment for them in CY 2005. For CY 2007 OPPS, CY 2005 claims data would be used as the basis for setting median costs for each CPT code, based on the reported charges reduced to cost, and would determine what APC configuration ensures most appropriate payment for the CPT drug administration codes. If hospitals do not bill charges in CY 2005 for the packaged drug administration CPT codes such as CPT codes 96412, 96423, 96545, or 90781, they would jeopardize our ability to make accurate payments for services billed and paid under these codes in CY 2007 when we use the CY 2005 data to set the payment weights.

Comment: Most commenters supported our proposal to code drug administration using CPT codes instead of the HCPCS codes. They indicated that it would be less burdensome for hospitals to code services using just one method for Medicare and all other payers. Some commenters opposed the use of CPT codes unless CMS pays an amount for each use of the CPT code, as CMS does under the Medicare Physician Fee Schedule.

Response: We cannot pay an amount for each use of each CPT code because all of our drug administration cost data are on a per visit (not a per code) basis as charges for each of the following three HCPCPS codes, Q0081, Q0083, and Q0084, are reported for a visit and not a service.

We agree that billing for drug administration using the CPT codes will be less burdensome to hospitals and will also facilitate development of more accurate payment rates for drug administration services in future years. For CY 2005 OPPS, we will collapse the CPT codes billed for drug administration into a single unit of the applicable APC for payment as we do not have the CPT code specific claims data for use in establishing a CPT code specific payment. However, we anticipate that we would have the necessary claims for CY 2007 OPPS to set an appropriate APC payment rate for the services described by the CPT codes.

Comment: Several commenters asked that we affirm that hospitals may report CPT codes 90780 (intravenous infusion for therapy/diagnosis administered by physician or under direct supervision of physician; up to one hour) and 90781 (each additional hour up to (8) hours), notwithstanding that the administration is not done by a physician or under the direct supervision of a physician. The commenters stated that such services are typically administered in hospitals by nurses without direct physician supervision and that if hospitals report these codes only when the full definition of the code is met, they would not be able to report the infusion services they furnish.

Response: We do not view the language of these CPT codes' definitions as being an obstacle to or inconsistent with the use of the codes by hospitals for billing Medicare. We view our general requirements regarding physician supervision (with respect to payment for services that are incident to a physician's service in the outpatient hospital setting) as meeting the

physician supervision aspect of the codes and thus, do not believe that use of the codes in the hospital outpatient setting would be prevented by the inclusion of the language in the code definition.

Comment: A commenter asked that we change the status indicator for CPT code 90780 and 90781 to ''X'' from ''T'' thereby eliminating the multiple procedure reduction for these codes, which in CY 2005 will replace HCPCS code Q0081 in billing for the administration of infusion therapy. The commenter stated that there is no situation in which the time and resources involved in infusion care should be reduced in the case of an observation patient.

Response: We disagree. The costs of space, utilities and staff attendance are duplicated when the beneficiary is receiving another service at the same time as infusion therapy, in particular when the patient is in observation. Hence it is appropriate to apply a multiple procedure reduction to infusion therapy particularly when the patient is in observation status. We believe it is necessary to understand how the OCE multiple procedure discounting logic functions. Line-items with a service indicator of ''T'' are subject to multiple procedure discounting unless modifiers 76, 77, 78, and/or 79 are present on the claim. The ''T'' line-item with the highest payment amount will not be discounted but all other ''T'' line items will be discounted as multiple procedures. All line-items that do not have a service indicator of ''T'' will be ignored in determining the discount. Therefore, if the only other services reported with infusion therapy are an emergency department or other visit code, or diagnostic tests and services assigned status indicator ''S,'' the infusion therapy code would not be subject to the multiple procedure discounting.

Comment: Several commenters stated that multiple visits per day for antibiotic infusion are common and the drug administration policies should permit such visits to be paid separately. The commenters stated that multiple visits for chemotherapy are possible and that provisions should be made for billing and paying them when they occur.

Response: We agree with the commenters on this issue. The reporting and payment for these multiple visits and services will not be an issue once payment for drug administration under the OPPS is made based on CPT code-specific data. However, until such time, hospitals will need to use modifier 59 (distinct procedure) when billing charges for services furnished during multiple visits that follow the initial visit. For CPT codes 90780 and 90781, where there are multiple visits for infusion on the same day, the hospital should report CPT code 90780 with modifier 59 and CPT code 90781, if appropriate, with modifier 59 for each separate visit for infusion. With modifier 59 appended to CPT codes 90780 and 90781, the OCE will allow up to 4 units of APC 0120 (Infusion of nonchemotherapy drugs) to be paid. Similarly, for the chemotherapy administration codes, where there is no modifier 59 reported, the OCE will collapse all codes that map to a particular APC into one unit of that APC and will pay one unit of each applicable APC. The system will assume that all services were furnished in one single encounter. Where the chemotherapy services are provided in multiple encounters, the hospital will need to show modifier 59 on the service furnished in the second encounter. The OCE will map those services into an additional unit of each applicable APC and will pay for each visit. The OCE will not, for a single date of service, pay more than 4 units of APC 120, nor more than 2 units of APCs 116 and 117 (chemotherapy by route other than infusion and infusion of chemotherapy drugs). We intend to reassess these limits based on provider feedback and our review of later claims data.

Comment: One commenter asked that CMS ensure that the costs for CPT code 90780 (Infusion therapy one hour) are included in payment for CPT codes 67221 (Ocular photodynamic therapy) and 67225 (Eye photodynamic therapy add-on) because CPT code 90780 is bundled into both of these procedure codes.

Response: The procedure code definition for CPT code 67221 specifies that intravenous infusion is included, and CPT code 67225 is to be listed separately in addition to CPT code 67221, if a second eye is treated. Therefore, the National Correct Coding Initiative (NCCI) edits preclude payment for CPT code 90780 with CPT codes 67221 and 67225 because the charges for the procedure CPT codes 67221 and 67225 are presumed to include all costs of administering the drug. Correct coding would not include reporting CPT code 90780 for the same visits when photodynamic therapy was provided. We expect that hospitals will include their charges for the necessary infusion in their charges for the procedure codes when they bill CPT codes 67221 or 67225, so that our claims data reflect the costs of all resources necessary to perform the services.

Comment: Several commenters urged CMS to adopt the new and revised AMA definitions for drug administration, which will be HCPCS G-codes in the CY 2005 Medicare Physician Fee Schedule, because the existing CPT codes do not adequately capture the costs of the range of drug administrations. They also urged CMS to educate providers on the correct use of the new CPT codes. The commenters indicated that implementing the new CPT codes for drug administration will be more difficult in hospitals than in physicians' offices because the services are typically provided in more places in hospitals than in physicians' offices.

Response: For CY 2005 OPPS, we are implementing the existing CPT codes for drug administration rather than the new G-codes that will be used for the Medicare Physician Fee Schedule payments. We do not intend to use the new HCPCS G-codes for the OPPS drug administration services until such time as the new CPT codes for those services are issued in CY 2006. We believe that it would be disruptive to hospitals if we required them to implement the HCPCS alphanumeric codes for drug administration in CY 2005 and then switch to the new CPT codes in CY 2006. While only a subset of the physician community administers anti-neoplastic drugs in their offices, we believe that most hospitals do so on an outpatient basis and hence most hospitals would have to change to the new HCPCS codes for CY 2005, only to change again to new CPT codes for CY 2006. However, we are told that all hospitals use the current CPT codes to bill other payers and crosswalk from the current CPT codes to the Q codes to bill Medicare. Thus, using the current CPT codes should be easier for hospitals than their current method for billing Medicare. This would not be the case if we were to require that they use the new HCPCS codes for drug administration.

Comment: One commenter indicated that CMS should revise the OPPS to mirror the policy under the Medicare Physician Fee Schedule that pays separately for each drug administered to permit the payment of one unit of each APC for each and every drug administered. The commenter stated that since CMS acknowledged that there are additional resources used with each administration of a drug, it should apply the same policy to hospitals since all of these services are furnished by nurses, whether in a physician's office setting or a hospital setting.

Response: We are moving to the use of CPT codes for CY 2005 OPPS. However, we will not be paying an APC amount for each unit of each CPT code.

The APC rate is, by necessity, based on historic data for a code that was billed and reported on a per visit basis. Therefore, to pay each unit of a CPT code an APC amount would not accurately reflect the resources used and would result in an overpayment of the costs of the services provided.

Comment: A commenter asked CMS to permit hospitals to continue billing HCPCS codes Q0081, Q0083 and Q0084 for drug administration until April 1, 2005 so that hospitals that do not currently bill the CPT codes for drug administration may have a transition period to convert to CPT code billing.

Response: The three cited Q-codes will be deactivated for the OPPS effective January 1, 2005 and therefore cannot be used up to April 1, 2005. As discussed in our proposed rule, we are eliminating the 90-day grace period for deleted codes effective January 1, 2005. We are adopting this policy because the Health Insurance Portability and Accountability Act (HIPAA) transaction and code set rules require usage of the medical code that is valid at the time that the service is provided. Details regarding elimination of the 90-day grace period for billing deleted codes were issued to our contractors on February 4, 2004, in Transmittal 89, Change Request 3093. Moreover, we are not aware that there are any hospitals that do not bill the CPT codes for drug administration, as hospitals have told us that all payers other than Medicare require that they use the CPT codes and will not accept the Q-codes.

Comment: A commenter asked that CMS use the first two quarters of the CY 2005 claims to set the median costs for drug administration in CY 2006 OPPS so that the transition to the more accurate payments under the CPT codes could begin earlier than CY 2007.

Response: As the CY 2005 claims data will be the basis for the CY 2007 payment weights, we regret that we are unable to transition to the new payments earlier than CY 2007 because of the time required to access the CY 2005 claims data and to process and construct our database for ratesetting and impact analyses. The second quarter of CY 2005 data will not be available to us until at least August 15, 2005, which is far too late for us to have developed and published any CY 2006 proposed rule.

After carefully reviewing all comments received, we are adopting as final our proposal to use the CPT codes for drug administration, effective January 1, 2005. We will collapse the CPT codes billed into a single unit of the applicable APC for payment. In addition, we are establishing the Q-code and APC crosswalk for CPT code 96549 and will be paying 1 unit of APC 0117 for CPT code 96410 (to which CPT code 96410 will be crosswalked). We will not make a separate payment for CPT code 96412 regardless of whether 1 unit or more units are billed. For CY 2005, CPT code 96412 will be a packaged and not paid separately. Further, when a hospital bills 3 units of CPT code 96400 (Chemotherapy administration, subcutaneous or intramuscular, with or without local anesthesia), the OCE will assign 1 unit of APC 0116 for that code and the payment will be based on HCPCS code Q0083, a per visit code. Modifier 59 may be used with codes in APCs 0116, 0117, and 0120 to signify additional encounters on the same date of service for which additional APC payments may be made.

Table 33 below contains the crosswalk of CPT codes for drug administration to drug administration APCs for CY 2005. The last two columns of this table indicate the maximum number of units of the APC that the OCE will assign without or with modifier 59, respectively.

BILLING CODE 4120–01–P

Table 33.--Crosswalk from CPT Codes for Drug Administration to Drug Administration APCs

CPT Code	Description	SI	APC	Corresponding HCPCS Code	OCE Maximum APC Units without Modifier 59	OCE Maximum APC Units with Modifier 59
96400	Chemotherapy, sc/im	S	116	Q0083	1	2
96405	Intralesional chemo admin	S	116	Q0083	1	2
96406	Intralesional chemo admin	S	116	Q0083	1	2
96408	Chemotherapy, push technique	S	116	Q0083	1	2
96410	Chemotherapy,infusion method	S	117	Q0084	1	2
96412	Chemo, infuse method add-on	N	--	--	0	0
96414	Chemo, infuse method add-on	S	117	Q0084	1	2
96420	Chemotherapy, push technique	S	116	Q0083	1	2
96422	Chemotherapy,infusion method	S	117	Q0084	1	2
96423	Chemo, infuse method add-on	N	--	--	0	0
96425	Chemotherapy,infusion method	S	117	Q0084	1	2
96440	Chemotherapy, intracavitary	S	116	Q0083	1	2
96445	Chemotherapy, intracavitary	S	116	Q0083	1	2
96450	Chemotherapy, into CNS	S	116	Q0083	1	2
96542	Chemotherapy injection	S	116	Q0083	1	2
96545	Provide chemotherapy agent	N	--	--	0	0
96549	Chemotherapy, unspecified	S	116	Q0083	1	2
90780	IV infusion therapy, 1 hour	T	120	Q0081	1	4
90781	IV infusion, additional hour	N	--	--	0	0

BILLING CODE 4120–01–C

I. Payment for Blood and Blood Products

Since the OPPS was first implemented in August 2000, separate payments have been made for blood and blood products in APCs rather than packaging them into payment for the procedures with which they were administered. Administrative costs for processing and storage specific to the transfused blood product are included in the blood product APC payment, which is based on hospitals' charges. Payment for the collection, processing, and storage of autologous blood, as described by CPT code 86890, is made

through APC 0347 (Level III Transfusion Laboratory Procedures).

In CY 2000, payments for bloods were established based on external data provided by commenters due to limited Medicare claims data. From CY 2000 to CY 2002, blood and blood product payment rates were updated for inflation. For CY 2003, as described in the November 1, 2002 final rule (67 FR 66773), we applied a special dampening methodology to blood and blood products that had significant reductions in payment rates from CY 2002 to CY 2003, when median costs were first calculated from hospital claims. Using the dampening methodology, we limited the decrease in payment rates for blood and blood products to approximately 15 percent. For CY 2004, as recommended by the APC Panel, we froze payment rates for blood and blood products at CY 2003 levels. This allowed us to undertake further study of the issues raised by commenters and presenters at the August 2003 and February 2004 APC Panel meetings.

In the August 16, 2004 proposed rule for CY 2005 OPPS, we proposed to continue to pay separately for blood and blood products. We also proposed to establish new APCs that would allow each blood product to be in its own separate APC, as several of the blood product APCs currently contained multiple blood products with no clinical homogeneity or whose product-specific median costs may not have been similar. Thus, we also proposed to reassign some of these HCPCS codes already contained in certain APCs to new APCs. (*See* Table 30 of the proposed rule (69 FR 50523.)

Other than for autologous blood products, hospital reimbursement for the costs of collection, processing, and storage of blood and blood products are made through the OPPS payments for specific blood product APCs. Wastage and other administrative costs for blood are attributable to overhead and distributed across all hospital services linked to cost centers in the Medicare cost report, through the standard process of converting charges to costs using hospitals' CCRs for each cost center on the cost report.

In the August 16, 2004 proposed rule, we noted that comments to previous OPPS rules had stated that the CCRs that we used to adjust claim charges to costs for blood in past years were too low, resulting in underestimation of the true hospital costs for blood and blood products. In response, we conducted a thorough analysis of the OPPS claims to compare CCRs between hospitals with a blood-specific cost center and hospitals defaulting to the overall hospital CCR. Our past methodology for determining CCRs for blood products included a default to the overall CCR when any given provider had chosen not to report costs and charges in a blood-specific cost center on the cost report. After matching the two blood-specific cost centers to the 38X and 39X revenue codes, we observed a significant difference in CCRs utilized for conversion of blood product charges to costs for those hospitals with and without blood-specific cost centers. The median CCR for those hospitals with a blood-specific cost center was 0.66 for revenue code 38X and 0.64 for revenue code 39X, and for those defaulting to the overall hospital CCR, the result was a CCR of 0.34 for revenue code 38X and 0.33 for revenue code 39X. The median overall CCR for all hospitals in the CY 2005 analysis was 0.33.

In light of this information, we applied the methodology described in our August 16, 2004 proposed rule to calculate simulated medians for each blood and blood product based on our CY 2003 claims data. We assumed that those hospitals not reporting costs and charges in a blood-specific cost center on their annual cost report, in general, face similar costs and engage in comparable charging practices for blood as those reporting a blood-specific cost center. For those hospitals not reporting a blood-specific cost center, we simulated a blood-specific CCR, which we then applied to convert charges to costs for blood products. Overall, this methodology increased the estimated median costs of blood and blood products by 25 percent for CY 2005 relative to the median costs used to set CY 2004 APC rates. For example, the estimated median for HCPCS code P9016 (Red blood cells, leukocyte reduced), the most frequently billed blood product, increased by 32 percent relative to the CY 2004 median.

As discussed in the proposed rule, in reviewing the simulated medians calculated using the methodology described above relative to those medians used to set CY 2004 payment rates, we noticed that some low-volume blood products (< 1,000 units) demonstrated significant decreases in median costs utilizing our general methodology. Overall, the simulated median costs for low-volume blood products declined by 14 percent for CY 2005. Because a small sample size can lead to great variability in point estimates, we sought to increase the number of units of low-volume blood products by combining CY 2002 and CY 2003 claims data for the low-volume products. We used the simulated CCRs to calculate costs from charges from CY 2002 and CY 2003 claims data. To ensure that we combined comparable costs, we updated the simulated costs on the CY 2002 claims to the base year of CY 2003 using the Producer Price Index (PPI) for blood and derivatives for human use (Commodity Code #063711). This is the PPI used to update blood and blood product prices in the market basket (67 FR 50039, August 1, 2002). We recognize that not all of the low-volume blood products had claims in CY 2002.

After combining the 2 years of claims data, we were able to raise the volume of blood units billed for several of these products above 1,000 units. Since the publication of the proposed rule, additional claims data from the last quarter of CY 2003 have become available to us. The data showed that a few of the blood products had utilization in CY 2003 that exceeded the 1,000 unit low-volume threshold and will not be subject to the low-volume blood product payment adjustment described below, that we are adopting for CY 2005. The low-volume blood products that we are adopting as final are listed below in Table 31 of this final rule with comment period.

The DHHS Advisory Committee on Blood Safety and Availability has recommended that CMS establish payment rates for blood and blood products based on current year acquisition costs and actual total costs of providing such blood products. At the February 2004 APC Panel meeting, the APC Panel recommended that CMS use external data to derive costs of blood and blood products in order to establish payment rates. At the September 2004 APC Panel meeting, the APC Panel recommended that CMS freeze payment rates for low-volume blood products for CY 2005 at CY 2004 levels. The Panel also recommended that CMS consider using external data for setting payment rates for blood and blood products in the future.

We received the following comments on our August 16, 2004 proposed rule regarding payment for blood and blood products.

Comment: A few commenters expressed strong support for payment rates developed using hospital data rather than blood industry data. The commenters urged CMS to exercise caution in using blood industry data and to consider evaluating the data for their validity, reliability and consistency with geographic variations in costs, in addition to being publicly available and subject to audit.

Response: We agree with the commenters that the OPPS payment rates should be based on the most

recently available and accurate hospital claims data. However, in rare circumstances when accurate hospital claims data capturing the full costs of services may not be available, we evaluate all external data very carefully to make sure that they meet our external data criteria. As discussed above, in setting all blood and blood product payment rates for CY 2005, we have relied upon data from hospital claims submitted to CMS.

Comment: Several commenters expressed concern about the proposed payment rates for blood and blood products. The commenters indicated that despite increases in the CY 2005 proposed payment rates for blood and blood products, the proposed payment rates still do not meet the actual costs to hospitals of acquiring these products. Some commenters stated that, in addition to hospital coding and billing problems, only a small number of hospitals were actually reporting blood costs, and that lack of reporting explains why the payment rates are still significantly below hospital acquisition costs. The commenters expressed concerns that this would create barriers to access to a safe blood supply for Medicare beneficiaries.

The commenters also expressed concerns about reductions in payment rates for low-volume blood products. They recommended that CMS either freeze payment rates at the CY 2004 OPPS levels for low-volume blood products that experienced a decrease in their proposed rates or use external data in setting payment rates for these products.

Response: We appreciate the commenters' concerns and share the same concern for protecting beneficiaries' access to a safe blood supply. As with all of the OPPS services, we prefer to rely on our claims data whenever possible. Comments received for previous rules also suggested that current hospital blood costs are not captured because hospitals underreport blood on their claims because it is too costly to bill for blood. However, our thorough analysis of billing for blood from CY 2003 claims data indicated that 81 percent of all hospitals included in our ratesetting and modeling for CY 2005 billed at least one unit of blood or blood product in CY 2003. Of these hospitals however, only 47 percent reported separate costs and charges in the two cost centers specific to blood on their most recent annual cost reports. It may be that those hospitals billing for blood but not reporting costs and charges on their cost reports for either of the two blood-specific cost centers reported their blood costs and charges under other cost centers, such as operating room. As discussed in the proposed rule, we simulated blood-specific hospital CCRs to account for these reporting differences and used these simulated CCRs to develop proposed median costs for blood products for CY 2005. Our claims data clearly show that the vast majority of hospitals do bill the OPPS for blood and blood products. In addition, the distribution of costs for individual products provides no evidence of significant coding problems.

As explained in the preamble of this section, we estimate that by using our new methodology of simulating medians and implementing the proposed payment rates for blood and blood products, excluding low-volume blood products, there would be a 25 percent increase in payment for blood and blood products overall. This includes a 32 percent increase in payment from CY 2004 for leukocyte reduced red blood cells (HCPCS code P9016), the highest volume blood product in the hospital OPD, and a 25 percent increase in payment for each unit of red blood cells (HCPCS code P9021), the second highest volume blood product.

After carefully reviewing all of the public comments received timely regarding low-volume blood products, we are convinced that due to the low utilization of these products, in addition to possible hospital coding and billing problems for these low-volume products, the claims data may not have captured the complete costs of these products to hospitals as fully as possible. We believe it is imperative that Medicare beneficiaries have full access to all medically necessary blood and blood products, including products that are infrequently utilized. Therefore, for blood products that would have experienced a decrease in median cost from CY 2004 to CY 2005 based on our proposed methodology, we are establishing CY 2005 payment rates that are adjusted to a 50/50 blend of CY 2004 product-specific OPPS median costs and our proposed CY 2005 simulated medians. This adjustment methodology will allow us to undertake further study of the issues raised by commenters and by presenters at the September 2004 APC Panel meeting, without putting beneficiary access to these low-volume blood products at risk.

Comment: One commenter suggested that CMS survey all hospitals across the country to investigate direct and indirect costs for blood. The commenter expressed concern that our proposed rates were insufficient to cover the costs of blood and its testing and storage. The commenter also expressed the need for continued increases in payments for blood products.

Response: We appreciate the commenter's recommendation and will take it into consideration as needed, when we reassess the payment rates for blood and blood products. While we believe our payment rates are appropriate and adequate for the provision of blood and blood product services, we are aware of the increasing number of tests required to ensure the safety of the nation's blood supply, which could possibly add to the costs of processing blood and blood products. The APC payment rates for blood and blood products are intended to cover the costs of medically necessary testing by community blood banks or blood banks operated by hospitals. However, the APC payment rates are not meant to include costs of tests requiring a specific patient's blood, such as cross-matching in preparation for transfusion, because these tests are separately payable under the OPPS.

Comment: Several commenters, including a hospital association, recommended that CMS issue more specific guidance to hospitals for billing of blood-related services in order to improve hospital claims data. Specifically, commenters requested that CMS address issues related to application of the Medicare blood deductible, differences between donor and nondonor states, hospital markups for blood costs, the appropriate use of HCPCS code P9011 (Split blood unit) in billing, blood processing and preparation costs and autologous blood collection. In addition, the same commenter recommended that CMS share its draft guidance for review with the Outpatient Medicare Technical Advisory Group (MTAG) or the National Uniform Billing Committee (NUBC), or both, to ensure it is correct, comprehensive, and reflective of the billing provider's perspective.

Response: We recognize the need for comprehensive billing guidelines for hospitals and other providers to address a variety of blood-related services under the OPPS. In the near future, we intend to provide further billing guidelines to clarify our original Program Transmittal A–01–50 issued on April 12, 2001 (CR Request 1585) regarding correct billing for blood-related services. We agree with the commenters and intend to gather information from all relevant and available resources.

Comment: One commenter, a hospital association, indicated that the revenue code 390 (Blood Storage and Processing) should not have been included in Table 18 (Proposed Packaged Services by

Revenue Codes) of the August 16, 2004 proposed rule. The commenter expressed concern that by including revenue code 390 in this table, hospitals would not be paid for the services because of a line-item claim rejection.

Response: We are clarifying that a HCPCS code billed with revenue codes listed in Table 18 of the proposed rule could be paid separately as long as the HCPCS code is not assigned a status indicator of ''N.'' When a revenue code charge is billed without a HCPCS code, the charge is reduced to cost using the appropriate CCR for the revenue code. This cost is then added to a line item charge (reduced to cost) for a separately payable HCPCS code. This allows costs associated with uncoded revenue code charges to be captured so we can make a more accurate payment for the claim. If we did not add the costs of the line item revenue code charges without HCPCS codes, the full cost data for all resources necessary to deliver a separately payable service might not be captured, possibly resulting in a lesser payment for the claim.

In summary, after carefully reviewing all public comments received timely, we are adopting as final for CY 2005 OPPS the following proposals:

- To continue to pay separately for blood and blood products, to establish new APCs that would place each blood product in its own separate APC, and to implement proposed APC reassignments for such blood and blood products.
- Effective for services furnished on or after January 1, 2005, in this final rule with comment period, we are providing that the payment rates for blood and blood products, excluding low-volume blood products whose CY 2005 simulated medians decreased from the CY 2004 medians, will be determined according to the methodology we described in the August 16, 2004 proposed rule.
- Effective for services furnished on or after January 1, 2005, in this final rule with comment period, we are providing that the CY 2005 payment rates for low-volume blood products that would have experienced a decrease in median costs from CY 2004 to CY 2005 based on our proposed methodology are adjusted to a 50/50 blend of CY 2004 product-specific median costs and our proposed CY 2005 simulated medians.

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Table 34.—CY 2005 APC Assignment of Blood and Blood Product Codes

HCPCS	Expired HCPCS	Status Indicator	Description	APC
P9010		K	Whole blood for transfusion	0950
P9011		K	Split unit of blood	0967
P9012		K	Cryoprecipitate each unit	0952
P9016		K	RBC leukocytes reduced	0954
P9017		K	Plasma 1 donor frz w/in 8 hr	9508
P9019		K	Platelets, each unit	0957
P9020		K	Plaelet rich plasma unit	0958
P9021		K	Red blood cells unit	0959
P9022		K	Washed red blood cells unit	0960
P9023		K	Frozen plasma, pooled, sd	0949
P9031		K	Platelets leukocytes reduced	1013
P9032		K	Platelets, irradiated	9500
P9033		K	Platelets leukoreduced irradiated	0968
P9034		K	Platelets, pheresis	9507
P9035		K	Platelet pheres leukoreduced	9501
P9036		K	Platelet pheresis irradiated	9502
P9037		K	Plate pheres leukoredu irradiated	1019
P9038		K	RBC irradiated	9505
P9039		K	RBC deglycerolized	9504
P9040		K	RBC leukoreduced irradiated	0969
P9043		K	Plasma protein fract,5%,50ml	0956
P9044		K	Cryoprecipitate reduced plasma	1009
P9048		K	Plasmaprotein fract,5%,250ml	0966
P9050		K	Granulocytes, pheresis unit	9506
P9051	C1010	K	Blood, L/R, CMV-NEG	1010
P9052	C1011	K	Platelets, HLA-m, L/R, unit	1011
P9053	C1015	K	Plt, pher, L/R, CMV, irradiated	1020
P9054	C1016	K	Blood, L/R, Froz/Degly/Washed	1016
P9055	C1017	K	Plt, Aph/Pher, L/R, CMV-Neg	1017
P9056	C1018	K	Blood, L/R, Irradiated	1018
P9057	C1020	K	RBC, frz/deg/wsh, L/R, irradiated	1021
P9058	C1021	K	RBC, L/R, CMV neg, irradiated	1022
P9059	C1022	K	Plasma, frz within 24 hour	0955
P9060	C9503	K	Fresh frozen plasma, ea unit	9503

Table 35.—Low Volume Blood and Blood Product Codes for CY 2005 Payments

HCPCS	Description
P9039	Red blood cells deglycerolized
P9043	Plasma protein fractionated, 5 percent, 50 ml
P9048	Plasmaprotein fractionated, 5 percent, 250 ml
P9050	Granulocytes, pheresis unit
P9053	Platelet, pher, L/R, CMV, irradiated
P9054	Blood, leukocyte reduced, frozen, deglycerolized, washed
P9055	Platelet, APH/PHER, leukocyte reduced, CMV, irradiated
P9057	RBC, frozen/deg/washed, L/R, irradiated
P9058	RBC, L/R CMV-neg, irradiated
P9059	Plasma, frozen within 24 hour
P9060	Fresh frozen plasma, each unit

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VI. Estimated Transitional Pass-Through Spending in CY 2005 for Drugs, Biologicals, and Devices

A. Basis for Pro Rata Reduction

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for a given year to an ''applicable percentage'' of projected total Medicare and beneficiary payments under the hospital OPPS. For a year before CY 2004, the applicable percentage is 2.5 percent; for CY 2004 and subsequent years, we specify the applicable percentage up to 2.0 percent.

If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a prospective uniform reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We make an estimate of pass-through spending to determine not only whether payments exceed the applicable percentage but also to determine the appropriate reduction to the conversion factor.

For devices, making an estimate of pass-through spending in CY 2005 entails estimating spending for two groups of items. The first group consists of those items for which we have claims data for procedures that we believe used devices that were eligible for pass-through status in CY 2003 and CY 2004 and that would continue to be eligible for pass-through payment in CY 2005. The second group consists of those items for which we have no direct claims data, that is, items that became, or would become, eligible in CY 2004 and would retain pass-through status in CY 2005, as well as items that would be newly eligible for pass-through payment beginning in CY 2005.

B. Estimate of Pass-Through Spending for CY 2005

In the August 16, 2004 proposed rule, we proposed to set the applicable percentage cap at 2.0 percent of the total OPPS projected payments for CY 2005. In this final rule with comment period, we are setting the applicable percentage cap at the same 2.0 percent.

We are using the same methodology described in the proposed rule to estimate the pass-through spending for CY 2005. To estimate CY 2005 pass-through spending for device categories in the first group described above, we used volume information from CY 2003 claims data for procedures associated with a pass-through device and manufacturer's price information from applications for pass-through status. This information was projected forward to CY 2005 levels, using inflation and utilization factors based on total growth in Medicare Part B as projected by the CMS Office of the Actuary (OACT).

To estimate CY 2005 pass-through spending for device categories included in the second group, that is, items for which we have no direct claims data, we used the following approach: For categories with no claims data in CY 2003 that would be active in CY 2005, we followed the methodology described in the November 2, 2001 final rule (66 FR 55857). That is, we used price information from manufacturers and volume estimates based on claims for procedures that would most likely use the devices in question. This information was projected forward to CY 2005 using the inflation and utilization factors supplied by the CMS OACT to estimate CY 2005 pass-through spending for this group of device categories. For categories that become eligible in CY 2005, we will use the same methodology. No new device categories for January 1, 2005, were announced after the publication of the proposed rule. Therefore, the estimate of pass-through spending does not incorporate any pass-through spending for categories made effective January 1, 2005.

With respect to CY 2005 pass-through spending for drugs and biologicals, as we explain in section V.A.3. of this final rule with comment period, the pass-through payment amount for new drugs and biologicals that we determine have pass-through status equals zero. Therefore, our estimate of total pass-through spending for drugs and biologicals with pass-through status in CY 2005 equals zero.

Table 36.--Estimates for CY 2005 Transitional Pass-Through Spending for Current Pass-Through Device Categories Continuing Into CY 2005

New HCPCS	APC	Existing Pass-Through Devices	CY 2005 Estimated Utilization	CY 2005 Anticipated Pass-through Payments
C1814	1814	Retinal tamponade device, silicone oil	33,865	$13,166,712
C1818	1818	Integrated keratoprosthesis device	5	$34,750
C1819	1819	Tissue localization excision device	10,979	$2,031,115

In accordance with the methodology described above, we estimate that total pass-through spending for devices in CY 2005 would equal approximately $23.4 million, which represents 0.10 percent of total OPPS projected payments for CY 2005. This figure includes estimates for the current device categories continuing into CY 2005, in addition to projections for categories that first become eligible during CY 2005. This estimate is significantly lower than previous year's estimates because of the method we discuss in section V.A.3. of this preamble for determining the amount of pass-through payment for drugs and biologicals with pass-through status in CY 2005.

Therefore, we will institute no pro rata reduction for CY 2005.

In section V.G. of this final rule with comment period, we indicate that we are accepting pass-through applications for new radiopharmaceuticals that are assigned a HCPCS code on or after January 1, 2005. The pass-through amount for new radiopharmaceuticals approved for pass-through status in CY 2005 would be the difference between the OPPS payment for the radiopharmaceutical, that is, the payment amount determined for the radiopharmaceutical as a sole source specified covered drug, and the payment amount for the radiopharmaceutical under section 1842(o) of the Act. However, we have no information identifying new radiopharmaceuticals to which a HCPCS code might be assigned after January 1, 2005 for which pass-through status would be sought. We also have no data regarding payment for new radiopharmaceuticals with pass-through status under the methodology that we specify in section V.G. However, we do not believe that pass-through spending for new radiopharmaceuticals in CY 2005 will be significant enough to materially affect our estimate of total pass-through spending in CY 2005. Therefore, we are not including radiopharmaceuticals in our estimate of pass-through spending in CY 2005.

Because we estimate pass-through spending in CY 2005 will amount to 0.10 percent of total projected OPPS CY 2005 spending, we are returning 1.90 percent of the pass-through pool to adjust the conversion factor, as we discuss in section VIII. of this preamble.

We received a few public comments on our estimate of CY 2005 pass-through spending for drugs, biologicals, and devices.

Comment: One commenter, a hospital organization, commended CMS for returning a portion of the pass-through pool that exceeds its estimate for pass-through payments for CY 2005, by increasing the conversion factor.

Response: We appreciate the commenter's support.

Comment: One commenter was concerned that CMS did not provide information on the extent to which amounts that are actually spent on pass-through payments and outlier payments compared to the amounts that are carved out of the total amount allowed OPPS payments for these projected payments. The commenter was concerned that the amounts carved out for these purposes may not actually be spent and thus would be lost to hospitals.

Response: We are required by law to estimate the amounts that we expect to spend on pass-through payments and outliers each year before the start of the calendar year. We share the commenter's interest in making those estimates as accurately as possible to ensure that hospitals receive the amount to which they are entitled. We make our final estimate for each calendar year to the best of our ability based on all of the most recently available data when we prepare our final rule, including comments we receive concerning those issues in response to the proposed rule. With respect to the availability of data, we have established limited data sets that include the set of claims we use for, first, the proposed rule and, ultimately, the final rule estimates. For example, the claims for CY 2003 used for the final rule for CY 2005 will be available to the public in a limited data set format. We will continue to assess the means by which we provide such information to determine if there are alternate ways to ensure that our stakeholders obtain the information that is important to them on a timely basis.

VII. Other Policy Decisions and Policy Changes

A. Statewide Average Default Cost-to-Charge Ratios

CMS uses cost-to-charge ratios (CCRs) to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS. Some hospitals do not have a valid CCR. These hospitals include, but are not limited to, hospitals that are new and have not yet submitted a cost report, hospitals that have a CCR that falls outside predetermined floor and ceiling thresholds for a valid CCR, or hospitals that have recently given up their all-inclusive rate status. When OPPS was first implemented in CY 2000, we used CY 1996 and CY 1997 cost reports to calculate default urban and rural CCRs for each State to use in determining the reasonable cost-based payments for those hospitals without a valid CCR (Program Memorandum A–00–63, CR 1310, issued on September 8, 2000). In the August 16, 2004 OPPS proposed rule, we proposed to update the default ratios for CY 2005.

As we proposed, in this final rule, we calculated the statewide default CCRs using the same CCRs that we use to adjust charges to costs on claims data. Table 31 lists the final CY 2005 default urban and rural CCRs by State. These CCRs are the ratio of total costs to total charges from each provider's most recently submitted cost report, for those cost centers relevant to outpatient services. We also adjusted these ratios to reflect final settled status by applying the differential between settled to submitted costs and charges from the most recent pair of settled to submitted cost reports.

The majority of submitted cost reports, 87 percent, were for CY 2002. We only used valid CCRs to calculate these default ratios. That is, we removed the CCRs for all-inclusive hospitals, CAHs, and hospitals in Guam and the U.S. Virgin Islands because these entities are not paid under the OPPS, or in the case of all-inclusive hospitals, because their CCRs are suspect. We further identified and removed any obvious error CCRs and trimmed any outliers. We limited the hospitals used in the calculation of the default CCRs to those hospitals that billed for services under the OPPS during CY 2003.

Finally, we calculated an overall average CCR, weighted by a measure of volume, for each State except Maryland. This measure of volume is the total lines on claims and is the same one that we use in our impact tables. Calculating a rate for Maryland presented a unique challenge. There are only a few providers in Maryland that are eligible to receive payment under the OPPS. However, we had no usable in-house cost report data for these Maryland hospitals, which is why we remove Maryland providers from our claims data for modeling OPPS. Therefore, we obtained data from the fiscal intermediary for Maryland, which we attempted to use in calculating the CCRs for Maryland, but which we ultimately determined could not be used to calculate representative CCRs. The cost data for three Maryland hospitals with very low volumes of services and cost data were so irregular that we lacked confidence that it would result in a valid statewide CCR. Thus, for Maryland, we used an overall weighted average CCR for all hospitals in the nation to calculate the weighted average CCRs appearing in Table 37. The overall decrease in default statewide CCRs can be attributed to the general decline in the ratio between costs and charges widely observed in the cost report data.

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Table 37.--Statewide Average Cost-to-Charge Ratios

State	Urban/Rural	Previous Default CCR	Default CCR
Alabama	RURAL	0.31552	0.26715
Alabama	URBAN	0.29860	0.24577
Alaska	RURAL	0.59388	0.61859
Alaska	URBAN	0.38555	0.42717
Arizona	RURAL	0.39748	0.32769
Arizona	URBAN	0.30922	0.26980
Arkansas	RURAL	0.35936	0.31754
Arkansas	URBAN	0.38278	0.30471
California	RURAL	0.40335	0.29314
California	URBAN	0.32427	0.24213
Colorado	RURAL	0.51041	0.43069
Colorado	URBAN	0.41863	0.32179
Connecticut	RURAL	0.42702	0.47250
Connecticut	URBAN	0.46592	0.44626
Delaware	RURAL	0.36289	0.36304
Delaware	URBAN	0.45061	0.45948
District of Columbia	URBAN	0.38690	0.37513
Florida	RURAL	0.31782	0.24304
Florida	URBAN	0.28363	0.22401
Georgia	RURAL	0.39829	0.33823
Georgia	URBAN	0.40262	0.32105
Hawaii	RURAL	0.44420	0.41027
Hawaii	URBAN	0.34815	0.34474
Idaho	RURAL	0.49682	0.46454
Idaho	URBAN	0.51942	0.49178
Illinois	RURAL	0.41825	0.34063
Illinois	URBAN	0.36825	0.29964
Indiana	RURAL	0.44596	0.36862
Indiana	URBAN	0.44205	0.37237
Iowa	RURAL	0.50166	0.41996
Iowa	URBAN	0.46963	0.38788
Kansas	RURAL	0.48065	0.38973
Kansas	URBAN	0.34698	0.29271

State	Urban/Rural	Previous Default CCR	Default CCR
Kentucky	RURAL	0.36987	0.31089
Kentucky	URBAN	0.37381	0.32476
Louisiana	RURAL	0.34317	0.29912
Louisiana	URBAN	0.34357	0.27736
Maine	RURAL	0.47857	0.38801
Maine	URBAN	0.54084	0.44897
Massachusetts	URBAN	0.44439	0.38812
Michigan	RURAL	0.44890	0.39418
Michigan	URBAN	0.41143	0.37428
Minnesota	RURAL	0.48514	0.47136
Minnesota	URBAN	0.45259	0.37416
Mississippi	RURAL	0.34264	0.30290
Mississippi	URBAN	0.37097	0.29322
Missouri	RURAL	0.42187	0.34160
Missouri	URBAN	0.38128	0.31081
Montana	RURAL	0.51173	0.47891
Montana	URBAN	0.49396	0.44817
Nebraska	RURAL	0.49386	0.42378
Nebraska	URBAN	0.42043	0.33875
Nevada	RURAL	0.42878	0.50623
Nevada	URBAN	0.22854	0.22333
New Hampshire	RURAL	0.50083	0.43585
New Hampshire	URBAN	0.39954	0.33224
New Jersey	URBAN	0.49024	0.34038
New Mexico	RURAL	0.44932	0.33899
New Mexico	URBAN	0.50857	0.43311
New York	RURAL	0.52062	0.43944
New York	URBAN	0.54625	0.42556
North Carolina	RURAL	0.37776	0.35416
North Carolina	URBAN	0.42726	0.38114
North Dakota	RURAL	0.52829	0.41175
North Dakota	URBAN	0.47341	0.36740
Ohio	RURAL	0.42562	0.41161
Ohio	URBAN	0.42718	0.32814
Oklahoma	RURAL	0.40628	0.32908
Oklahoma	URBAN	0.36264	0.29193
Oregon	RURAL	0.47915	0.42468
Oregon	URBAN	0.49958	0.43762
Pennsylvania	RURAL	0.40582	0.36015
Pennsylvania	URBAN	0.33807	0.28011
Puerto Rico	URBAN	0.42208	0.41376

State	Urban/Rural	Previous Default CCR	Default CCR
Rhode Island	URBAN	0.43930	0.35106
South Carolina	RURAL	0.35996	0.29377
South Carolina	URBAN	0.36961	0.29167
South Dakota	RURAL	0.49599	0.39218
South Dakota	URBAN	0.44259	0.33947
Tennessee	RURAL	0.36663	0.30294
Tennessee	URBAN	0.36464	0.28313
Texas	RURAL	0.41763	0.33642
Texas	URBAN	0.33611	0.30306
Utah	RURAL	0.49748	0.47097
Utah	URBAN	0.46733	0.45230
Vermont	RURAL	0.47278	0.46757
Vermont	URBAN	0.54533	0.44259
Virginia	RURAL	0.39408	0.33502
Virginia	URBAN	0.38604	0.32559
Washington	RURAL	0.54246	0.43429
Washington	URBAN	0.54658	0.41362
West Virginia	RURAL	0.42671	0.35073
West Virginia	URBAN	0.45616	0.40700
Wisconsin	RURAL	0.50126	0.42304
Wisconsin	URBAN	0.46268	0.38487
Wyoming	RURAL	0.54596	0.51581
Wyoming	URBAN	0.41265	0.41087

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Comment: Several commenters recommended that CMS instruct fiscal intermediaries to work with those facilities that have given up their all-inclusive rate status to quickly determine an appropriate CCR that will provide an accurate estimate of costs for each facility.

Response: We have already instructed intermediaries to update CCRs in a timely manner. In Program Memorandum A–03–004 dated January 17, 2003, we instructed fiscal intermediaries to recalculate each provider's CCR on an ongoing basis whenever a more recent full year cost report becomes available, which includes tentatively settled cost reports. Fiscal intermediaries will calculate a hospital-specific CCR for all-inclusive rate hospitals, as with all hospitals relying on default CCRs, when their first tentatively settled cost report becomes available after no longer being considered as all-inclusive rate hospitals.

Comment: A few commenters asserted that the decrease in CCRs between 1996 and 2002 was caused by the fact that charges were increasing faster than costs and that the increase in charges has been much lower since 2003. They requested that CMS take this fact into account in developing default CCRs.

Response: We did not inflate charges when calculating the default CCRs, and therefore, we do not believe that there is a need to adjust for charge inflation since CY 2002.

B. Transitional Corridor Payments: Technical Change

1. Provisions of the August 16, 2004 Proposed Rule

When the OPPS was implemented, every provider was eligible to receive an additional payment adjustment (or transitional corridor payment) if the payments it received under the OPPS were less than the payment it would have received for the same services under the prior reasonable cost-based system (section 1833(t)(7) of the Act). Transitional corridor payments were intended to be temporary payments for most providers but permanent payments for cancer and children's hospitals to ease their transition from the prior reasonable cost-based payment system to the prospective payment system. Section 411 of Pub. L. 108–173 amended section 1833(t)(7)(D)(i) of the Act to extend such payments through December 31, 2005, for rural hospitals with 100 or fewer beds and extended such payments for services furnished during the period that begins with the provider's first cost reporting period beginning on or after January 1, 2004 and ends on December 31, 2005, for sole community hospitals located in rural areas. Accordingly, transitional corridor payments are only available to children's hospitals, cancer hospitals, rural hospitals having 100 or fewer beds, and sole community hospitals located in rural areas.

At the time the OPPS was implemented, section 1833(t)(7)(F)(ii) of the Act defined the payment-to-cost ratio (PCR) used to calculate the ''pre-BBA amount'' [2] for purposes of calculating the transitional corridor

[2] Section 1833(t)(7) of the Act defined the ''pre-BBA'' amount for a period as the amount equal to the product of (1) the payment-to-cost ratio for the hospital based on its *cost reporting period ending in 1996,* and (2) the reasonable cost of the services for the period. (Emphasis added.) In this context, BBA refers to the Balanced Budget Act of 1997, Pub. L. 105–33, enacted on August 5, 1997.

payments to be determined using the payments and reasonable costs of services furnished during the provider's cost reporting period ending in calendar year 1996. The BIPA, Pub. L. 106–554, enacted on December 21, 2000, revised that requirement. Section 403 of BIPA amended section 1833(t)(7)(F)(ii)(I) of the Act to allow transitional corridor payments to hospitals subject to the OPPS that did not have a 1996 cost report by authorizing use of the first available cost reporting period ending after 1996 and before 2001 in calculating a provider's PCR.

Although we discussed the BIPA amendment in the CY 2002 OPPS proposed rule published on August 24, 2001 (66 FR 44674), and implemented the amendment through Program Memorandum No. A–01–51, issued on April 13, 2001, we failed to revise the regulations at § 419.70(f)(2) to reflect the change. In the August 16, 2004 OPPS proposed rule, we proposed a technical correction to § 419.70(f)(2) to conform it to the provision of section 1833(t)(7)(F)(ii)(I) of the Act.

We did not receive any comments on this proposed technical change. Accordingly, in this final rule with comment period, we are adopting as final without modification our proposal and correcting § 419.70(f)(2) to conform it to the provision of section 1833(t)(7)(F)(ii)(I) of the Act.

However, we did receive several comments on the proposed rule related to the transitional corridor payments.

Comment: A few commenters expressed appreciation for the extension of transitional corridor payments for children's hospitals, cancer hospitals, rural hospitals having 100 or fewer beds, and sole community hospitals located in rural areas, but requested that CMS consider extending payment protections to rural hospitals that are not eligible for transitional corridor payments. The commenters noted that rural hospitals that have converted to critical access hospitals are paid at cost and, therefore, have a competitive advantage over rural hospitals that are not eligible for transitional corridor payments and cannot convert to critical access hospital status. One commenter requested protection for rural hospitals that provide emergency services.

A few commenters noted that the transitional corridor payment provision for rural hospitals having 100 or fewer beds and sole community hospitals located in rural areas expires on December 31, 2005, and requested that CMS further extend this payment protection.

Response: We share the concerns of rural hospitals and do not intend to limit access to health care to beneficiaries in rural areas. However, we note that the statute is very specific and does not provide transitional corridor payments for entities other than those listed in the statute, nor extend transitional corridor payments past December 31, 2005, for rural or sole community hospitals.

2. Comments on the Provisions of the January 6, 2004 Interim Final Rule With Comment Period

As discussed in the January 6, 2004 interim final rule with comment period (69 FR 828), section 411(a)(1)(B) of Pub. L. 108–173 provided that hold harmless transitional corridor provisions shall apply to sole community hospitals located in rural areas. Section 411(a)(2) states that the effective date for section 411(a)(1)(B) ''shall apply with respect to cost reporting periods beginning on or after January 1, 2004'' for sole community hospitals located in rural areas. The Conference Agreement for Pub. L. 108–173 states, ''The hold harmless provisions are extended to sole community hospitals located in a rural area starting for services furnished on or after January 1, 2004 * * *''

Comment: Commenters noted that there appears to be a discrepancy between the effective date in section 411 of Pub. L. 108–173 and the Conference Agreement. The commenters noted that, in accordance with section 411, a sole community hospital with a cost reporting period beginning on a date other than January 1 will not receive transitional corridor payments and ''interim'' transitional corridor payments for services furnished after December 31, 2003, and before the beginning of the provider's next cost reporting period.

Response: Section 411(a)(2) of Pub. L. 108–173 provides the effective date with respect to the transitional corridor payments applied to sole community hospitals. Specifically, a sole community hospital with a cost reporting period beginning on or after April 1, 2004, is subject to the hold harmless provisions. We note that if a hospital qualifies as both a rural hospital having 100 or fewer beds and as a sole community hospital located in a rural area, for purposes of receiving transitional corridor payments and interim transitional corridor payments, the hospital will be treated as a rural hospital having 100 or fewer beds. In this case, transitional corridor payments would begin on January 1, 2004, and there would be no gap in transitional corridor payments.

C. Status Indicators and Comment Indicators Assigned in the Outpatient Code Editor (OCE)

1. Payment Status Indicators

The payment status indicators (SIs) that we assign to HCPCS codes and APCs under the OPPS play an important role in determining payment for services under the OPPS because they indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. As we proposed, for CY 2005, we are providing our status indicator assignments for APCs in Addendum A, for the HCPCS codes in Addendum B, and the definitions of the status indicators in Addendum D1 to this final rule with comment period.

Payment under the OPPS is based on HCPCS codes for medical and other health services. These codes are used for a wide variety of payment systems under Medicare, including, but not limited to, the Medicare fee schedule for physician services, the Medicare fee schedule for durable medical equipment and prosthetic devices, and the Medicare clinical laboratory fee schedule. For purposes of making payment under the OPPS, we must be able to signal the claims processing system through the Outpatient Code Editor (OCE) software, as to HCPCS codes that are paid under the OPPS and those codes to which particular OPPS payment policies apply. We accomplish this identification in the OPPS through the establishment of a system of status indicators with specific meanings. Addendum D1 contains the definitions of each status indicator for purposes of the OPPS for CY 2005.

We assign one and only one status indicator to each APC and to each HCPCS code. Each HCPCS code that is assigned to an APC has the same status indicator as the APC to which it is assigned.

In the August 16, 2004 OPPS proposed rule, for CY 2005, we proposed to use the following status indicators in the specified manner:

- ''A'' to indicate services that are paid under some payment method other than OPPS, such as under the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) fee schedule or the Medicare Physician Fee Schedule. Some, but not all, of these other payment systems are identified in Addendum D1 to this final rule with comment period.
- ''B'' to indicate the services that are not payable under the OPPS when submitted on an outpatient hospital Part B bill type, but that may be payable by

fiscal intermediaries to other provider types when submitted on an appropriate bill type.

- ''C'' to indicate inpatient services that are not payable under the OPPS.
- ''D'' to indicate a code that is discontinued, effective January 1, 2005.
- ''E'' to indicate items or services that are not covered by Medicare or codes that are not recognized by Medicare.
- ''F'' to indicate acquisition of corneal tissue, which is paid on a reasonable cost basis and certain CRNA services that are paid on a reasonable cost basis.
- ''G'' to indicate drugs, biologicals, and radiopharmaceutical agents that are paid under the OPPS transitional pass-through rules.
- ''H'' to indicate devices that are paid under the OPPS transitional pass-through rules and brachytherapy sources that are paid on a cost basis.
- ''K'' to indicate drugs, biologicals (including blood and blood products), and radiopharmaceutical agents that are paid in separate APCs under the OPPS, but that are not paid under the OPPS transitional pass-through rules.
- ''L'' to indicate flu and pneumococcal immunizations that are paid at reasonable cost but to which no coinsurance or copayment apply.
- ''N'' to indicate services that are paid under the OPPS, but for which payment is packaged into another service or APC group.
- ''P'' to indicate services that are paid under the OPPS, but only in partial hospitalization programs.
- ''S'' to indicate significant procedures that are paid under the OPPS, but to which the multiple procedure reduction does not apply.
- ''T'' to indicate significant services that are paid under the OPPS and to which the multiple procedure payment discount under the OPPS applies.
- ''V'' to indicate medical visits (including emergency department or clinic visits) that are paid under the OPPS.
- ''X'' to indicate ancillary services that are paid under the OPPS.
- ''Y'' to indicate nonimplantable durable medical equipment that must be billed directly to the durable medical equipment regional carrier rather than to the fiscal intermediary.

We proposed the payment status indicators identified above for each HCPCS code and each APC in Addenda A and B and requested comments on the appropriateness of the indicators we have assigned.

We received several public comments on our proposal relating to status indicators.

Comment: Two commenters, representing radionuclide, radiopharmaceutical, and nuclear medicine interests, expressed concern about assignment of status indicator ''N'' in Transmittal 290, issued August 27, 2004, to the new revenue codes for diagnostic and therapeutic radiopharmaceuticals, revenue codes 0343 and 0344, that were effective October 1, 2004. The commenters recommended changing the status indicators for both 0343 and 0344 to ''K'' for nonpass-through drugs, biologicals, and radiopharmaceutical agents, and asked that CMS clarify and notify hospitals to use these revenue codes when billing and reporting costs for radiopharmaceuticals that can be paid separately. The commenters also stated that clarifying that these are nonpass-through and not packaged will assist CMS in tracking and analyzing costs for the radiopharmaceuticals and contribute to more accurate payment determinations. They recommended that CMS require hospitals to use the new revenue codes to report charges for radiopharmaceuticals.

Response: The assignment of status indicator ''N'' to revenue codes 0343 and 0344 in Transmittal 290 relates to OCE treatment of lines on a claim that report a charge with a revenue code but with no HCPCS code. The assignment of certain status indicators to revenue codes reported in the attachment to quarterly OPPS updates entitled ''Summary of Data Modifications'' is an OCE specification only, and should not be confused with how we use the status indicators listed in Addendum D1 that we assign to HCPCS codes and to APCs.

Additional information related to how revenue codes are used can be found in Pub. 100–04, Medicare Claims Processing, Chapter 4, Section 20, Subsection 5.1.1, entitled ''Packaged Revenue Codes.'' As indicated in that section, certain revenue codes when reported on an OPPS bill *without* a HCPCS code, including revenue codes 0343 and 0344, are considered packaged services that are to be factored into the transitional outpatient payment and outlier calculations.

Although we strongly encourage hospitals to report charges and HCPCS codes for diagnostic and therapeutic radiopharmaceuticals using revenue codes 0343 and 0344, respectively, we generally try to not to impose requirements on the assignment of HCPCS codes to revenue codes for OPPS services because the way hospitals assign costs varies so widely. Nevertheless, we agree with the commenters that, to the extent hospitals report charges for radiopharmaceuticals, both packaged and separately payable, using the new revenue codes 0343 and 0344, our cost data related to radiopharmaceuticals should be more precise.

We will review our manual instructions and previous issuances related to the reporting of revenue codes and make any revisions needed to clarify and update those instructions.

Comment: One commenter asked that CMS change the status indicator for code 90780 and 90781 to ''X'' from ''T'' and thereby cease the application of the multiple procedure reduction to these services, which will be billed for administration of infusion therapy in place of Q0081 for CY 2005. The commenter indicated that there is no situation in which the time and resources involved in infusion care should be reduced in the case of an observation patient.

Response: We disagree. The costs of space, utilities and staff attendance are duplicated when the beneficiary is receiving another service at the same time as infusion therapy, in particular when the patient is in observation. Hence, a multiple procedure reduction to infusion therapy is appropriate, particularly when the patient is in observation status. However, we are noting how the multiple procedure discounting logic in the OCE functions. Line items with a service indicator of ''T'' are subject to multiple procedure discounting unless modifiers 76, 77, 78, or 79, or all, are present. The ''T'' line item with the highest payment amount will not be multiple procedure discounted, and all other ''T'' line items will be multiple procedure discounted. All line items that do not have a service indicator of ''T'' will be ignored in determining the discount. Therefore, if the only other services reported with infusion therapy are an emergency department or other visit code, or diagnostic tests and services assigned status indicator ''S,'' the infusion therapy code would not be subject to the multiple procedure discounting.

2. Comment Indicators

In the November 1, 2002 and the November 7, 2003 final rules with comment period, which implemented changes in the OPPS for CYs 2003 and 2004, respectively, we provided code condition indicators in Addendum B. The code condition indicators and their meaning are as follows:

- ''DG''—Deleted code with a grace period; Payment will be made under the deleted code during the 90-day grace period.

• ''DNG''—Deleted code with no grace period; Payment will not be made under the deleted code.

• ''NF''—New code final APC assignment; Comments were accepted on a proposed APC assignment in the Proposed Rule; APC assignment is no longer open to comment.

• ''NI''—New code interim APC assignment; Comments will be accepted on the interim APC assignment for the new code.

Medicare had permitted a 90-day grace period after implementation of an updated medical code set, such as the HCPCS, to give providers time to incorporate new codes in their coding and billing systems and to remove the discontinued codes. HCPCS codes are updated annually every January 1, so the grace period for billing discontinued HCPCS was implemented every January 1 through March 31.

The Health Insurance Portability and Accountability Act (HIPAA) transaction and code set rules require usage of the medical code set that is valid at the time that the service is provided. Therefore, effective January 1, 2005, CMS is eliminating the 90-day grace period for billing discontinued HCPCS codes. Details about elimination of the 90-day grace period for billing discontinued HCPCS codes were issued to our contractors on February 6, 2004, in Transmittal 89, Change Request 3093.

In order to be consistent with the HIPPA rule that results in the elimination of the 90-day grace period for billing discontinued HCPCS codes, in the August 16, 2004 OPPS proposed rule, we proposed, effective January 1, 2005, to delete code condition indicators ''DNG'' and ''DG''. We proposed to designate codes that are discontinued effective January 1, 2005 with status indicator ''D,'' as described in section VII.C.1. of this preamble.

Further, we proposed to rename ''code condition'' indicators as ''comment indicators.'' In Addendum D2 to this final rule with comment period, we list the following two comment indicators that we had proposed to use to identify HCPCS codes assigned to APCs that are or are not subject to comment:

• ''NF''—New code, final APC assignment; Comments were accepted on a proposed APC assignment in the Proposed Rule; APC assignment is no longer open to comment.

• ''NI''—New code, interim APC assignment; Comments will be accepted on the interim APC assignment for the new code.

We did not receive any public comments on our proposal relating to comment indicators. We are implementing the comment indicators and discontinuing the use of code condition indicators as we proposed, without modification.

D. Observation Services

Frequently, beneficiaries are placed in ''observation status'' in order to receive treatment or to be monitored before making a decision concerning their next placement (that is, admit to the hospital or discharge). This status assignment occurs most frequently after surgery or a visit to the emergency department. For a detailed discussion of the clinical and payment history of observation services, see the November 1, 2002 final rule with comment period (67 FR 66794).

Before the implementation of the OPPS in CY 2000, payment for observation care was made on a reasonable cost basis, which gave hospitals a financial incentive to keep beneficiaries in ''observation status'' even though clinically they were being treated as inpatients. With the initiation of the OPPS, observation services were no longer paid separately; that is, they were not assigned to a separate APC. Instead, costs for observation services were packaged into payments for the services with which the observation care was associated.

Beginning in early 2001, the APC Panel began discussing the topic of separate payment for observation services. In its deliberations, the APC Panel asserted that observation services following clinical and emergency room visits should be paid separately, and that observation following surgery should be packaged into the payment for the surgical procedure. For CY 2002, we implemented separate payment for observation services (APC 0339) under the OPPS for three medical conditions: chest pain, congestive heart failure, and asthma. A number of accompanying requirements were established, including the billing of an evaluation and management visit in conjunction with the presence of certain specified diagnosis codes on the claim, hourly billing of observation care for a minimum of 8 hours up to a maximum of 48 hours, timing of observation beginning with the clock time on the nurse's admission note and ending at the clock time on the physician's discharge orders, a medical record documenting that the beneficiary was under the care of a physician who specifically assessed patient risk to determine that the beneficiary would benefit from observation care, and provision of specific diagnostic tests to beneficiaries based on their diagnoses. In developing this policy for separately payable observation services, we balanced issues of access, medical necessity, potential for abuse, and the need to ensure appropriate payment. We selected the three medical conditions, noted previously, and the accompanying diagnosis codes and diagnostic tests to avoid significant morbidity and mortality from inappropriate discharge while, at the same time, avoiding unnecessary inpatient admissions.

Over the past 2 years, we have continued to review observation care claims data for information on utilization and costs, along with additional information provided to us by physicians and hospitals concerning our current policies regarding separately payable observation services. Our primary goal is to ensure that Medicare beneficiaries have access to medically necessary observation care. We also want to ensure that separate payment is made only for beneficiaries actually receiving clinically appropriate observation care.

In January 2003, the APC Panel established an Observation Subcommittee. Over the last year, this subcommittee has held discussions concerning observation care and reviewed data extracted from claims that reported observation services. The subcommittee presented the results of its deliberations to the full APC Panel at the February 2004 meeting. The APC Panel recommendations regarding observation care provided under the OPPS were broad in scope and included elimination of the diagnosis requirement for separate payment for observation services, elimination of the requirement for the concomitant diagnostic tests for patients receiving observation care, unpackaging of observation services beyond the typical expected recovery time from surgical and interventional procedures, and modification of the method for measuring beneficiaries' time in observation to make it more compatible with routine hospital practices and their associated electronic systems.

In response to the APC Panel recommendations, we undertook a number of studies regarding observation services, while acknowledging data limitations from the brief 2-year experience the OPPS has had with separately payable observation services.

To assess the appropriateness of the APC Panel's recommendation not to pay separately for observation services following surgical or interventional procedures, we analyzed the claims for these procedures to determine the extent to which the claims reported packaged observation services codes. This analysis revealed that while

observation services are being reported on some claims for surgical and interventional procedures, the great majority of claims for these procedures reported no observation services. The packaged status of these observation services codes may result in underreporting their frequency, but the proportion of surgical and interventional procedures reported with the packaged observation services codes was so small that any increase would not change our substantive conclusion. This confirmed our belief that, although an occasional surgical case may require a longer recovery period than expected for the procedure, as a rule, surgical outpatients do not require observation care. Given the rapidly changing nature of outpatient surgical and interventional services, it would be difficult to determine an expected typical recovery time for each procedure. We have concerns about overutilization of observation services in the post-procedural setting as partial replacement for recovery room time. However, we noted that, to the extent observation care or extended recovery services are provided to surgical or interventional patients, the cost of that care is packaged into the payment for the procedural APC which may result in higher median costs for those procedures.

We also analyzed the possibility of expanding the list of medical conditions for separately payable visit-related observation services, altering the requirements for diagnostic tests while in observation, and modifying the rules for counting time in observation care.

We looked at CY 2003 OPPS claims data for all packaged visit-related observation care for all medical conditions in order to determine whether or not there were other diagnoses that would be candidates for separately payable observation services. Our analysis confirmed that the three diagnoses that are currently eligible for separate payment for observation services are appropriate, as those diagnoses are frequently reported in our visit-related claims with packaged observation services. In fact, diagnoses related to chest pain were, by far, the diagnosis most frequently reported for observation care, either separately payable or packaged. Other diagnoses that appeared in the claims data with packaged observation services included syncope and collapse, transient cerebral ischemia, and hypovolemia.

The packaged status of those observation stays means that the data are often incomplete and the frequency of services may be underreported. Generally, information about packaged services is not as reliably reported as is that for separately paid services. However, we are not convinced that, for those other conditions (such as hypovolemia, syncope and collapse, among others), there is a well-defined set of hospital services that are distinct from the services provided during a clinic or emergency room visit. Separately payable observation care must include specific, clinically appropriate services, and we are still accumulating data and experience for the three medical conditions for which we are currently making separate payment. Therefore, we believed it was premature to expand the conditions for which we would separately pay for visit-related observation services.

Hospitals have indicated that, even in the cases where the diagnostic tests have been performed, to assure that billing requirements for separately payable observation services under APC 0339 are met, they must manually review the medical records to prepare the claims. If they do not conduct this manual review, they may not be coding appropriately for separately payable observation services.

As noted in our August 16, 2004 proposed rule, we have also received comments from the community and the APC Panel asserting that the requirements for diagnostic testing are overly prescriptive and administratively burdensome, and that hospitals may perform tests to comply with the CMS requirements, rather than based on clinical need. For example, a patient admitted directly to observation care with a diagnosis of chest pain may have had an electrocardiogram in a physician's office just prior to admission to observation and may only need one additional electrocardiogram while receiving observation care. Thus, two more electrocardiograms performed in the hospital as required under the current OPPS observation policy might not be medically necessary.

We continue to believe that the diagnostic testing criteria we established for the three medical conditions are the minimally appropriate tests for patients receiving a well-defined set of hospital observation services for those conditions. The previous example, notwithstanding, we also continue to believe that the majority of these tests would be performed in the hospital outpatient setting. We define observation care as an active treatment to determine if a patient's condition is going to require that he or she be admitted as an inpatient or if the condition resolves itself and the patient is discharged. The currently required diagnostic tests reflect that an active assessment of the patient was being undertaken, and we believe they are generally medically necessary to determine whether a beneficiary will benefit from being admitted to observation care and aid in determining the appropriate disposition of the patient following observation care.

After careful consideration, we agree that specifying which diagnostic tests must be performed as a prerequisite for payment of APC 0339 may be imposing an unreasonable reporting burden on hospitals and may, in some cases, result in unnecessary tests being performed. Therefore, in the August 16, 2004 proposed rule, we proposed, beginning in CY 2005, to remove the current requirements for specific diagnostic testing, and to rely on clinical judgment in combination with internal and external quality review processes to ensure that appropriate diagnostic testing (which we expect would include some of the currently required diagnostic tests) is provided for patients receiving high quality, medically necessary observation care.

Accordingly, we proposed that, beginning in CY 2005, the following tests would no longer be required to receive payment for APC 0339 (Observation):

- For congestive heart failure, a chest x-ray (71010, 71020, 71030), and electrocardiogram (93005) and pulse oximetry (94760, 94761, 94762)
- For asthma, a breathing capacity test (94010) or pulse oximetry (94760, 94761, 94762)
- For chest pain, two sets of cardiac enzyme tests; either two CPK (82550, 82552, 82553) or two troponins (84484, 84512) and two sequential electrocardiograms (93005)

We believe that this proposed policy change would benefit hospitals because it would reduce administrative burden, allow more flexibility in management of beneficiaries in observation care, provide payment for clinically appropriate care, and remove a requirement that may have resulted in duplicative diagnostic testing.

We received numerous public comments supporting our proposed policy. We did not receive any comments that opposed the proposed policy. Therefore, we are adopting, without modification, our proposal to no longer require specified diagnostic tests to receive payment for APC 0339, beginning in CY 2005.

Hospitals and the APC Panel further suggested that we modify the method for accounting for the beneficiary's time in observation care. Currently, hospitals report the time in observation beginning with the admission of the beneficiary to

observation and ending with the physician's order to discharge the patient from observation. There are two problems related to using the time of the physician discharge order to determine the ending time of observation care. First, providers assert that it is not possible to electronically capture the time of the physician's orders for discharge. As a result, manual medical record review is required in order to bill accurately. Second, the hospital may continue to provide specific discharge-related observation care for a short time after the discharge orders are written and, therefore, may not be allowed to account for the full length of the observation care episode. In an effort to reduce hospitals' administrative burden related to accurate billing, in the proposed rule, we proposed to modify our instructions for counting time in observation care to end at the time the outpatient is actually discharged from the hospital or admitted as an inpatient. Our expectation was that specific, medically necessary observation services were being provided to the patient up until the time of discharge. However, we did not expect reported observation time to include the time patients remain in the observation area after treatment is finished for reasons that include waiting for transportation home.

Although beneficiaries may be in observation care up to 48 hours or longer, we believed that, in general, 24 hours was adequate for the clinical staff to determine what further care the patient needs. In CY 2005, we proposed to continue to make separate payment for observation care based on claims meeting the requirement for payment of HCPCS code G0244 (Observation care provided by a facility to a patient with CHF, chest pain, or asthma, minimum 8 hours, maximum 48 hours). However, we proposed not to include claims reporting more than 48 hours of observation care in calculating the final payment rate for APC 0339.

We received several public comments on our proposal.

Comment: A number of commenters urged that CMS include claims for stays greater than 48 hours in the data used to calculate the payment rate for observation because any such claims in our dataset would have withstood local fiscal intermediary scrutiny for reasonableness and medical necessity and should therefore be regarded as legitimate for pricing calculations. One commenter requested that CMS provide clarification to fiscal intermediaries regarding billing for stays that exceed 48 hours because code G0244 (Observation care provided by a facility to a patient with CHF, chest pain or asthma, minimum 8 hours, maximum 48 hours) would seem to preclude billing G0244 for stays that exceed 48 hours but that otherwise meet all the criteria for payment.

Response: In an effort to clarify the apparent confusion cited by commenters with regard to billing for stays that exceed 48 hours, beginning in CY 2005, we are changing the descriptor for HCPCS code G0244 to read as follows:

G0244, Observation care provided by a facility to a patient with CHF, chest pain or asthma, minimum 8 hours.

We expect that hospitals will report one unit of G0244 for each hour of observation care provided to patients for congestive heart failure, chest pain, or asthma, with a minimum 8 units billed to be eligible for separate observation payment.

We carefully considered the comments that urged us to include reporting more than 48 hours to calculate the median cost of G0244. The final payment rate for APC 0339 listed in Addendum A is based on all CY 2003 claims for G0244 taken from the National Claims History file, without regard to units of service. Prior to implementation of the OPPS, when hospital outpatient services were paid on a reasonable cost basis, Medicare did allow payment for observation services that exceeded 48 hours when medical review determined that a more extended period of observation care was reasonable and necessary. Since implementation of the OPPS, Medicare has ceased paying separately for observation care, with the exception of services reported with G0244, because payment for observation services was packaged into payment for services with which observation services were reported. We believe that, in the overwhelming majority of cases, decisions can be and are routinely made in less than 48 hours whether to release a beneficiary from the hospital following resolution of the reason for the outpatient visit or whether to admit the beneficiary as an inpatient. Therefore, we intend to revisit this issue in future updates.

For the reasons stated above, we are not adopting as final for CY 2005, our proposal to exclude claims for G0244 that reported more than 48 hours of observation from calculation of the median cost for APC 0339.

We also proposed the following requirements to receive separate payment for HCPCS code G0244 in APC 0339 for medically necessary observation services involving specific goals and a plan of care that are distinct from the goals and plan of care for an emergency department, physician office, or clinic visit:

- The beneficiary must have one of three medical conditions: congestive heart failure, chest pain, or asthma. The hospital bill must report as the admitting or principal diagnosis an appropriate ICD–9–CM code to reflect the condition. The eligible ICD–9–CM diagnosis codes for CY 2005 are shown in Table 38 below.
- The hospital must provide and report on the bill an emergency department visit (APC 0610, 0611, or 0612), clinic visit (APC 0600, 0601, or 0602), or critical care (APC 0620) on the same day or the day before the separately payable observation care (G0244) is provided. For direct admissions to observation, in lieu of an emergency department visit, clinic visit, or critical care, G0263 (Adm with CHF, CP, asthma) must be billed on the same day as G0244.
- HCPCS code G0244 must be billed for a minimum of 8 hours.
- No procedures with a 'T' status indicator, except the code for infusion therapy of other than a chemotherapy drug (CPT code 90780) can be reported on the same day or day before observation care is provided.
- Observation time must be documented in the medical record and begins with the beneficiary's admission to an observation bed and ends when he or she is discharged from the hospital.
- The beneficiary must be in the care of a physician during the period of observation, as documented in the medical record by admission, discharge, and other appropriate progress notes that are timed, written, and signed by the physician.
- The medical record must include documentation that the physician explicitly assessed patient risk to determine that the beneficiary would benefit from observation care.

We received numerous public comments on our proposal.

Comment: Most commenters applauded our proposal to eliminate the requirement that specified diagnostic tests be reported in order to receive payment for HCPCS code G0244. However, many commenters expressed disappointment that CMS did not propose to expand the conditions for which separate payment would be provided for observation care. One commenter, representing cancer centers, requested that CMS study febrile neutropenia, chemotherapy hypersensitivity reaction, hypovolemia, and electrolyte imbalance as conditions that would warrant separate payment for observation. A few commenters